UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2026

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ____ to ____

Commission File Number 001-39531

Processa Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**45-1539785**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

601 21st Street, Suite 300 Vero Beach, FL 32960
(Address of Principal Executive Offices, Including Zip Code)

(772) 453-2899
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	PCSA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of outstanding shares of the registrant's common stock at November 9, 2026 was 2,798,241.

PROCESSA PHARMACEUTICALS, INC.
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Part I: Financial Information

Item 1: Financial Statements

Processa Pharmaceuticals, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except shares and per share amounts)

	September 30, 2026 *(unaudited)*	December 31, 2025
ASSETS		
Current Assets		
Cash and cash equivalents	$ 180,205	$ 5,537
Prepaid expenses and other	1,374	134
Digital assets at fair value	431	-
Total Current Assets	182,010	5,671
Digital assets at fair value	-	1,145
Prepaid expenses	-	994
Equipment, net	3	4
Total Assets	$ 182,013	$ 7,814
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities		
Accounts payable	$ 1,193	$ 1,057
Accrued expenses	670	1,180
Total Current Liabilities	1,863	2,237
Total Liabilities	1,863	2,237
Commitments and Contingencies (Note 10)	-	-
Temporary Equity		
Series A preferred stock, par value $0.0001; 307,063.330 shares and no shares were designated as of September 30, 2026 and December 31, 2025, respectively; and 306,574.202 shares and no shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	361,534	-
Stockholders' (Deficit) Equity		
Preferred stock, par value $0.0001, 692,936.67 shares authorized; no shares issued or outstanding at September 30, 2026 or December 31, 2025	-	-
Common stock, par value $0.0001, 1,000,000,000 shares authorized; 2,798,241 issued and outstanding at September 30, 2026; 2,572,114 issued and 2,571,914 outstanding at December 31, 2025	-	-
Additional paid-in capital	109,219	106,660
Accumulated other comprehensive loss	(20)	-
Treasury stock	-	(300)
Accumulated deficit	(290,583)	(100,783)
Total Stockholders' (Deficit) Equity	(181,384)	5,577
Total Liabilities, Temporary Equity, and Stockholders' (Deficit) Equity	$ 182,013	$ 7,814

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)
(in thousands, except shares and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating Expenses				
Research and development expenses	$ 1,811	$ 1,662	$ 4,270	$ 5,697
Acquired in-process research and development expenses	178,030	-	178,030	-
General and administrative expenses	4,288	1,827	7,497	4,590
Operating Loss	(184,129)	(3,489)	(189,797)	(10,287)
Other Income (Expense), net				
Unrealized loss on digital assets	(41)	-	(869)	-
Realized loss on digital assets	-	-	(159)	-
Other income	-	6	15	14
Interest income, net	1,013	46	1,010	68
Total other income (expense)	972	52	(3)	82
Net Loss	(183,157)	(3,437)	(189,800)	(10,205)
Other comprehensive loss, net of tax	(20)	-	(20)	-
Comprehensive loss	$ (183,177)	$ (3,437)	$ (189,820)	$ (10,205)
Net Loss per Common Share, Basic and Diluted	$ (61.58)	$ (1.81)	$ (68.18)	$ (10.48)
Weighted Average Common Shares Used to Compute Net Loss Applicable to Common Shares, Basic and Diluted	2,974,188	1,901,098	2,783,977	973,548

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Changes in Temporary Equity and Stockholders' (Deficit) Equity
(Unaudited)
(in thousands, except shares and per share amounts)

	Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock		Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Shares	Amount	Deficit	Total
Balance at January 1, 2025	-	$ -	148,308	$ -	$ 89,215	$ -	(200)	$ (300)	$ (87,219)	$ 1,696
Stock-based compensation	-	-	473	-	228	-	-	-	-	228
Shares issued in connection with capital raise, net	-	-	62,267	-	4,439	-	-	-	-	4,439
Shares withheld to pay income taxes on stock-based compensation	-	-	(72)	-	(1)	-	-	-	-	(1)
Net loss	-	-	-	-	-	-	-	-	(2,834)	(2,834)
Balance, March 31, 2025	-	-	210,976	-	93,881	-	(200)	(300)	(90,053)	3,528
Stock-based compensation	-	-	5,741	-	203	-	-	-	-	203
Shares issued in connection with capital raise, net	-	-	1,395,760	-	6,320	-	-	-	-	6,320
Shares withheld to pay income taxes on stock-based compensation	-	-	(887)	-	(9)	-	-	-	-	(9)
Net loss	-	-	-	-	-	-	-	-	(3,934)	(3,934)
Balance, June 30, 2025	-	-	1,611,590	-	100,395	-	(200)	(300)	(93,987)	6,108
Stock-based compensation	-	-	59	-	303	-	-	-	-	303
Shares issued in connection with capital raises and warrant exercises, net	-	-	503,090	-	2,860	-	-	-	-	2,860
Net loss	-	-	-	-	-	-	-	-	(3,437)	(3,437)
Balance, September 30, 2025	-	$ -	2,114,739	$ -	$ 103,558	-	(200)	$ (300)	$ (97,424)	$ 5,834

	Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Treasury Stock		Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Shares	Amount	Deficit	Total
Balance at January 1, 2026	-	$ -	2,572,114	$ -	$ 106,660	$ -	(200)	$ (300)	$ (100,783)	$ 5,577
Stock-based compensation	-	-	1,281	-	96	-	-	-	-	96
Shares issued in connection with capital raise, net	-	-	86,956	-	200	-	-	-	-	200
Shares sold to officers, directors, and employees	-	-	17,796	-	45	-	-	-	-	45
Shares withheld to pay income taxes on stock-based compensation	-	-	(112)	-	-	-	-	-	-	-
Retirement of treasury stock	-	-	(200)	-	(300)	-	200	300	-	-
Net loss	-	-	-	-	-	-	-	-	(3,377)	(3,377)
Balance, March 31, 2026	-	-	2,677,835	-	106,701	-	-	-	(104,160)	2,541
Stock-based compensation	-	-	812	-	92	-	-	-	-	92
Shares sold to officers and employees	-	-	64,409	-	162	-	-	-	-	162
Shares issued in connection with capital raise, net	-	-	50,330	-	153	-	-	-	-	153
Net loss	-	-	-	-	-	-	-	-	(3,266)	(3,266)
Balance, June 30, 2026	-	-	2,793,386	-	107,108	-	-	-	(107,426)	(318)
Stock-based compensation	-	-	4,855	-	846	-	-	-	-	846
Fair value of options assumed in Vidya Acquisition	-	-	-	-	1,280	-	-	-	-	1,280
Issuance of Series A preferred stock in connection with Vidya acquisition and PIPE transaction, net	306,574.202	361,534	-	-	-	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	(20)	-	-	-	(20)
Other	-	-	-	-	(15)	-	-	-	-	(15)
Net loss	-	-	-	-	-	-	-	-	(183,157)	(183,157)
Balance, September 30, 2026	306,574.202	$ 361,534	2,798,241	$ -	$ 109,219	$ (20)	-	$ -	$ (290,583)	$ (181,384)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Processa Pharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine months ended September 30,	
	2026	2025
Cash Flows From Operating Activities		
Net Loss	$ (189,800)	$ (10,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	1
Non-cash lease expense for right-of-use assets	-	71
Unrealized loss on digital assets	869	-
Realized loss on digital assets	159	-
Stock-based compensation	1,034	734
Acquired in-process research and development	178,030	-
Net changes in operating assets and liabilities:		
Prepaid expenses and other	1,916	690
Operating lease liability	-	(67)
Accounts payable	(2,349)	(154)
Accrued expenses	(623)	445
Net cash used in operating activities	(10,763)	(8,485)
Cash Flows From Investing Activities		
Net cash paid in connection with asset acquisition	(1,898)	-
Purchase of digital assets	(500)	-
Cash received from sale of digital assets	186	-
Net cash used in investing activities	(2,212)	-
Cash Flows From Financing Activities		
Net proceeds from issuance of common stock	560	13,619
Shares withheld to pay taxes on stock-based compensation	-	(10)
Proceeds from issuance of temporary equity	187,148	-
Payment of finance lease obligation	-	(7)
Other	(15)	-
Net cash provided by financing activities	187,693	13,602
Effect of exchange rate changes on cash and cash equivalents	(50)	-
Net Increase in Cash and Cash Equivalents	174,668	5,117
Cash and Cash Equivalents - Beginning of Period	5,537	1,191
Cash and Cash Equivalents - End of Period	$ 180,205	$ 6,308
Supplemental Cash Flow Information:		
Cash paid for interest	$ 20	$ 6
Cash paid for income taxes	$ -	$ -
Supplemental Non-Cash Investing Activities:		
Net liabilities assumed in connection with asset acquisition	$ 365	$ -

The accompanying notes are an integral part of these condensed consolidated financial statements.

Note 1 – Organization and Summary of Significant Accounting Policies

Organization

Processa Pharmaceuticals, Inc. (the "Company," "we," "us," and "our") is a clinical-stage pharmaceutical company advancing differentiated therapeutic programs for immunological and inflammatory diseases. On July 28, 2026, we acquired Vidya Therapeutics, Inc. ("Vidya"), a private company pursuant to the terms of an Agreement and Plan of Merger, dated as of July 28, 2026 (the "Merger Agreement" and the transaction consummated pursuant to the Merger Agreement, the "Vidya Acquisition") by and among the Company, Vidya, and certain merger subsidiaries that were party to the Merger Agreement.

The Vidya Acquisition brought into our pipeline Vidya's lead asset, VT-7208, an orally available, covalently binding, irreversible, central nervous system ("CNS")-penetrant Bruton's tyrosine kinase inhibitor ("BTKi") rationally designed to optimize for selectivity, potency, and tolerability. In connection with the Vidya Acquisition, we received $200.0 million in gross proceeds from a concurrent private placement financing of shares of our non-voting convertible preferred stock (the "2026 Private Placement"). We intend to use the net proceeds of $187.1 million from the private placement to fund operations into the second half of 2029 and through key clinical milestones, including top-line data from Phase 2 proof-of-concept clinical trials of VT-7208 for food allergy, chronic spontaneous urticaria ("CSU"), and relapsing multiple sclerosis ("RMS").

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions of the Securities and Exchange Commission ("SEC") on Form 10-Q and Article 8 of Regulation S-X.

Accordingly, they do not include all the information and disclosures required by U.S. GAAP for complete financial statements. All material intercompany accounts and transactions have been eliminated in consolidation. In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all adjustments necessary, which are of a normal and recurring nature, for the fair presentation of our financial position and of the results of operations and cash flows for the periods presented. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any other interim period or for the full year.

Liquidity

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. We have incurred losses since inception. We have an accumulated deficit of $290.6 million at September 30, 2026. During the nine months ended September 30, 2026, we generated a net loss of $189.8 million and used $10.8 million in net cash for operating activities from continuing operations. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future.

On July 30, 2026, we closed the 2026 Private Placement, as described in Note 2, for gross proceeds of $200.0 million from which we received net proceeds of $187.1 million. At September 30, 2026, we had cash and cash equivalents totaling $180.2 million, which management believes will fund our planned operations for at least one year from the issuance date of these financial statements.

The Series A Preferred Stock are convertible into shares of common stock, subject to receiving stockholder approval of the issuance of shares of common stock upon conversion of Series A Preferred Stock and exercise of the Assumed Options (see Note 2 for additional information on the planned proposals for the stockholder meeting). Under the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Designation"), if we fail to deliver to the holder of the Series A Preferred Stock shares of our common stock underlying such shares of Series A Preferred Stock at any time nine months after the initial issuance of the Series A Preferred Stock, holders of the Series A Preferred Stock are entitled to require us to make cash payments by wire transfer of immediately available funds equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares, subject to the applicable conversion-notice and delivery requirements, exceptions and availability of legally available funds. As a result, we concluded that the proceeds received from the private placement financing cannot be relied upon to mitigate the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within our control. Our plan to address this potential cash-settlement obligation is to obtain the requisite stockholder approval at a meeting expected to take place in the first quarter of 2027 and thereafter complete the conversion of the Series A Preferred Stock and delivery of the underlying common stock, subject to applicable beneficial ownership limitations. Accordingly, we concluded that substantial doubt about our ability to continue as a going concern continues to exist within one year after the date these financial statements are available to be issued.

Use of Estimates

In preparing our condensed consolidated financial statements and related disclosures in conformity with U.S. GAAP and pursuant to the rules and regulations of the SEC, we make estimates and judgments that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Estimates are used for, but not limited to preclinical and clinical trial expenses, stock-based compensation, intangible assets, future milestone payments and income taxes. These estimates and assumptions are continuously evaluated and are based on management's experience and knowledge of the relevant facts and circumstances. While we believe the estimates to be reasonable, actual results could differ materially from those estimates and could impact future results of operations and cash flows.

Digital Assets

Our digital assets consist of Chiliz (CHZ) tokens and we have accounted for them in accordance with Accounting Standards Codification ("ASC") 350-60, *Intangibles – Goodwill and Other – Crypto Assets*. We initially recorded the digital assets at cost and have subsequently remeasured at fair value as of the balance sheet date with changes in fair value recognized as unrealized gains or losses in the condensed consolidated statement of operations. During the nine months ended September 30, 2026, we sold 11 million CHZ tokens for $0.2 million and recognized a realized loss of $0.2 million related to the sale. We will continue to recognize any realized gains or losses in the consolidated statement of operations based on the fair value of the digital assets on the date of sale or derecognition. We have now classified the digital assets as a current asset, as we expect to realize the tokens in cash within a year.

Income Taxes

We account for income taxes in accordance with ASC Topic 740, *Income Taxes.* Deferred income taxes are recorded for the expected tax consequences of temporary differences between the basis of assets and liabilities for financial reporting purposes and amounts recognized for income tax purposes. At September 30, 2026 and December 31, 2025, we recorded a valuation allowance equal to the full recorded amount of our net deferred tax assets since it is more-likely-than-not that such benefits will not be realized. The valuation allowance is reviewed quarterly and is maintained until sufficient positive evidence exists to support its reversal.

Under ASC 740-270, *Income Taxes – Interim Reporting*, we are required to project our annual federal and state effective income tax rate and apply it to the year-to-date ordinary operating tax basis loss before income taxes. Based on the projection, no current income tax benefit or expense is expected for 2026 and the foreseeable future since we expect to generate taxable net operating losses.

Concentration of Credit Risk

Financial instruments that potentially subject us to significant concentration of credit risk consist primarily of our cash and cash equivalents. We utilize only well-established banks and financial institutions with high credit ratings. Balances on deposit are insured by the Federal Deposit Insurance Corporation (FDIC) up to specified limits. Total cash held by our banks at September 30, 2026 exceeded FDIC limits.

Recent Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2024-03 *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. This ASU is intended to improve the disclosures related to expenses and provide investors more detailed information about certain types of expenses. This ASU is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the potential impact that this new standard will have on its consolidated financial statements and related disclosures.

Note 2 – Acquisition of Vidya Therapeutics, Inc. and Concurrent Private Placement

As described in Note 1, "Organization and Summary of Significant Accounting Policies," on July 28, 2026, we acquired Vidya pursuant to the Merger Agreement. Under the terms of the Merger Agreement, we issued to the stockholders of Vidya an aggregate of 142,254.972 shares of Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"). Each share of Series A Preferred Stock is convertible into 1,000 shares of our common stock, par value $0.0001 per share, subject to receiving approval by our stockholders of the issuance of shares of our common stock upon conversion of Series A Preferred Stock and exercise of certain options held by the former equity holders of Vidya that we assumed in the Vidya Acquisition. All the outstanding options to purchase Vidya common stock were assumed by us and were converted into options to purchase an aggregate of 1,047,524 shares of our common stock (the "Assumed Options"). The total consideration in connection with the Vidya Acquisition was $175.4 million. We also incurred fees totaling $2.7 million in acquisition costs, of which $0.7 million was paid via 544.551 shares of Series A Preferred Stock to an advisor.

Pursuant to the Merger Agreement, we agreed to hold a stockholders' meeting to submit certain matters to our stockholders for consideration, including (i) the issuance of shares of our common stock upon conversion of the Series A Preferred Stock issued in connection with the Vidya Acquisition and exercise of certain Assumed Options pursuant to Nasdaq Listing Rules 5635(a) and 5635(b) (the "Preferred Stock Conversion Proposal"), (ii) the issuance of shares of our common stock upon conversion of the Series A Preferred Stock issued in connection with the 2026 Private Placement pursuant to Nasdaq Listing Rule 5635(d) (the "Minimum Price Proposal"), (iii) approval of the our 2027 Equity Incentive Plan (the "2027 Plan Proposal"), and (iv) approval of the 2027 Employee Stock Purchase Plan (the ("2027 ESPP Proposal" and, collectively with the Preferred Stock Conversion Proposal, the Minimum Price Proposal and the 2027 Plan Proposal, the "Stockholder Matters").

Subject to the receipt of stockholder approval of the Stockholder Matters, each share of Series A Preferred Stock will automatically convert into 1,000 shares of our common stock, subject to certain beneficial ownership limitations established by each holder. As a result of the acquisition and related private placement transaction, our equity holders immediately prior to the Vidya Acquisition owned approximately 1.4% of our common stock, equity holders of Vidya immediately prior to the Vidya Acquisition owned approximately 46.0% of our common stock and investors in the 2026 Private Placement owned approximately 52.6% of our common stock, in each case, calculated on a fully diluted basis (assuming the conversion in full of the Series A Preferred Stock) and based on our and Vidya's implied equity values.

The transaction was accounted for as an asset acquisition in accordance with ASC 805, *Business Combinations*. Upon completion of the Vidya Acquisition, we obtained control of Vidya's assets, consisting primarily of in-process research and development ("IPR&D"). We acquired one asset, the underlying intellectual property associated with Vidya's lead asset, VT-7208, an orally available, covalently binding, irreversible, CNS-penetrant BTKi that comprised more than 90% of Vidya's assets. Under this method of accounting, the Company was the accounting acquirer for financial reporting purposes. This determination was primarily based on the facts that, immediately following the Vidya Acquisition: (i) our stockholders hold the majority of the voting rights in the combined company based on their ownership, (ii) Vidya held only one out of the six board of director seats of the combined company, and (iii) the Company's existing executive management team continued in its respective leadership roles following closing and no former Vidya executive was appointed to a key executive management position of the combined company. In accordance with ASC 805, under the asset acquisition method of accounting, the assets acquired and liabilities assumed are recognized and measured at fair value and no goodwill is recorded or recognized.

Transaction costs of $2.7 million were capitalized as part of the cost of the assets acquired and, together with the acquired IPR&D, were expensed at the acquisition date because the IPR&D has no alternative future use. No goodwill was recognized. We have included the operating results of Vidya since July 28, 2026 in our consolidated financial statements.

The following summarizes the purchase price paid in the Vidya Acquisition (in thousands, except share and per share amounts):

Number of shares of Series A Preferred Stock issued to the Vidya shareholders and option holders, as converted		142,254,972
Multiplied by the fair value per share of our Series A Preferred Stock[(1)]	$	1.22119
Fair value of Series A Preferred Stock issued to effect the Vidya Acquisition		173,720
Fair value of the options to purchase Vidya common stock we assumed		1,280
Purchase Price	$	175,000

(1) The fair market valuation of the Series A Preferred Stock was determined based on the contractual conversion price per share, on an as-converted basis (1,000 shares of common stock for 1 share of Series A Preferred Stock).

The preliminary fair value of the net assets, liabilities, and IPR&D acquired was as follows (in thousands):

Cash acquired	$	(102)
Net liabilities assumed		467
IPR&D[(2)]		175,000
Net liabilities and IPR&D acquired	$	175,365

(2) Represents the Vidya Acquisition research and development projects which were in process, but not yet completed, and which we may advance following the Vidya Acquisition, including the development of VT-7208. The fair value of IPR&D projects acquired in an asset acquisition with no alternative future use are charged to expense on the acquisition date. Substantially all of the fair value of the gross assets acquired was concentrated in the acquired IPR&D, a single identifiable asset, and the transaction therefore passed the screen test under ASC 805. Accordingly, the acquired set of assets did not meet the definition of a business. Additionally, the acquired assets did not include the outputs or meaningful processes necessary to be considered a business under ASC 805. The IPR&D was recorded at the fair value of the consideration given.

Concurrently with the Vidya Acquisition, on July 30, 2026, we completed the 2026 Private Placement, pursuant to a Securities Purchase Agreement, dated July 28, 2026 for a $200.0 million private placement financing, under which we agreed to sell an aggregate of 163,774.679 shares of Series A Preferred Stock (or 163,774,679 shares of our common stock on an as-converted basis and without giving effect to any beneficial ownership limitations) at a price of $1,221.19 per share (or $1.22119 per share on an as-converted basis).

Note 3 – Series A Preferred Stock

Amendments to our Certificate of Incorporation - Series A Non-Voting Convertible Preferred Stock

In connection with the Vidya Acquisition and the 2026 Private Placement, on July 28, 2026, we filed a Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Delaware, as adopted by our board of directors (the "Board"). The Certificate of Designation provided for the creation of our Series A Preferred Stock.

Holders of Series A Preferred Stock are entitled to receive dividends on shares of Series A Preferred Stock equal to, on an as-if-converted-to-Common-Stock basis, and in the same form as dividends actually paid on shares of our common stock. Except as otherwise provided in the Certificate of Designation or as otherwise required by the General Corporation Law of the State of Delaware, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock: (i) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, amend its certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (ii) issue additional shares of Series A Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series A Preferred Stock, (iii) prior to the Automatic Conversion (as defined below), consummate either: (A) any Fundamental Transaction (as defined in the Certificate of Designation) or (B) any merger or consolidation with or into another person or any stock sale to, or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, share exchange or scheme of arrangement) with or into, another person in which our shareholders immediately before such transaction do not hold at least a majority of the voting power of our capital stock or surviving corporation or the parent entity of ours or surviving corporation immediately after such transaction or in which we or the surviving corporation issues securities in such transaction that represent, or are convertible into securities representing, more than a majority of the voting power of the Company immediately before such transaction, (iv) prior to the stockholder approval of the Preferred Stock Conversion Proposal, authorize or issue any class or series of stock that has powers, preferences or rights that are senior to those of the Series A Preferred Stock, (v) amend, waive or modify the Merger Agreement in any manner that would be reasonably likely to prevent, impede or materially delay stockholder approval of the Preferred Stock Conversion Proposal or the Automatic Conversion (as defined below) or (vi) enter into any agreement with respect to any of the foregoing.

At 5:00 pm Eastern time on the third business day following stockholder approval of the Preferred Stock Conversion Proposal, each share of Series A Preferred Stock will automatically convert into 1,000 shares of our common stock, subject to certain limitations (the "Automatic Conversion"), including that a holder of Series A Preferred Stock is prohibited from converting shares of Series A Preferred Stock into shares of our common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be established by the holder between 4.9% and 19.9%) of the total number of shares of our common stock issued and outstanding immediately after giving effect to such conversion (the "Beneficial Ownership Limitation"); provided that following stockholder approval of the Preferred Stock Conversion Proposal, such Beneficial Ownership Limitation may be waived by each holder of Series A Preferred Stock upon written notice to the Company to be effective on the 61st day following receipt of such notice.

If at any time nine months after the initial issuance of the Series A Preferred Stock, the Company fails to deliver to the holder of the Series A Preferred Stock shares of common stock underlying such shares of Series A Preferred Stock, then (other than in certain circumstances set forth in the Certificate of Designation), the Company will pay, at the request of such holder, an amount of cash by wire transfer of immediately available funds equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares, subject to the applicable conversion-notice and delivery requirements, exceptions and availability of legally available funds.

Note 4 – Stockholders' Equity

Common Stock

During the nine months ended September 30, 2026, we issued the following shares of common stock (in thousands, except share amounts unless otherwise noted):

- We sold a cumulative 169,161 shares of our common stock to certain investors in private placement transactions for a total of $0.4 million in net proceeds;
- We also sold 50,330 shares of common stock under our ATM Offering for approximately $0.2 million in net proceeds; and
- We issued a cumulative 6,836 shares of common stock to our directors, and certain employees for restricted stock units that reached the distribution requirement, net of 112 shares of common stock withheld for income and Federal Insurance Contributions Act taxes.

Treasury Stock

On February 15, 2026, our Board approved the retirement of the 200 shares held in treasury stock.

Note 5 - Stock-based Compensation

On June 19, 2019, our stockholders approved, and we adopted, the Processa Pharmaceuticals Inc. 2019 Omnibus Equity Incentive Plan (the "2019 Plan"). The 2019 Plan allows us, under the direction of our Board or a committee thereof, to make grants of stock options, restricted and unrestricted stock and other stock-based awards to employees, including our executive officers, consultants and directors. The 2019 Plan provides for the aggregate issuance of 632,000 shares of our common stock. At September 30, 2026, we had 200,000 shares available for future grants.

Stock Compensation Expense

We recorded stock-based compensation expense for the three and nine months ended September 30, 2026 and 2025 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 179	$ 110	$ 213	$ 166
General and administrative	667	193	821	568
Total	$ 846	$ 303	$ 1,034	$ 734

Stock Options

The following table summarizes our stock option activity during the nine months ended September 30, 2026:

	Total options Outstanding	Weighted average exercise price	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2026	136,372	$ 13.43	9.8
Options assumed in the Vidya Acquisition	1,047,524	0.01	9.4
Outstanding as of September 30, 2026	1,183,896	1.56	9.3
Exercisable as of September 30, 2026	58,745	19.59	9.3

No forfeiture rate was applied to these stock options. The aggregate intrinsic value of outstanding options, other than those assumed in the Vidya Acquisition, was $0 at both September 30, 2026 and 2025. No stock options were exercised during the nine months ended September 30, 2026 or 2025. At September 30, 2026, unrecognized stock-based compensation expense for stock options of approximately $3.2 million is expected to be fully recognized over a weighted average period of 2.6 years.

Restricted Stock Units

Activity with respect to our restricted stock units ("RSUs") during the nine months ended September 30, 2026 was as follows:

	Number of shares	Weighted-average grant-date fair value per share
Outstanding at January 1, 2026	56,641	$ 31.02
Granted	232,721	2.60
Forfeited	(312)	201.72
Distributed, net	(6,836)	173.39
Outstanding at September 30, 2026	282,214	3.95
Vested and unissued	(236,679)	3.69
Unvested at September 30, 2026	45,535	$ 5.30

On July 26, 2026, we granted RSUs that represent 232,721 shares of common stock to our employees and directors with a grant date fair value of $2.60. The RSUs vested immediately and the shares of common stock will be distributed within six months of the grant date. At September 30, 2026, unrecognized stock-based compensation expense of approximately $0.2 million for RSUs is expected to be fully recognized over a weighted average period of 2.0 years.

Holders of our vested RSUs will be issued shares of our common stock upon meeting the distribution restrictions contained in their restricted stock unit award agreement. The distribution restrictions are different (longer) than the vesting schedule, imposing an additional restriction on the holder. While certain employees may hold fully vested RSUs, the individual does not hold any shares or have any rights of a stockholder until the distribution restrictions are met. Upon distribution to the employee, each RSU converts into one share of our common stock. The RSUs contain dividend equivalent rights.

Warrants

During the nine months ended September 30, 2026, warrants to purchase 27,065 shares of common stock expired or were cancelled. We did not grant any warrants and no warrants were exercised. We did not have any unrecognized stock-based compensation expense related to the 1,410,066 outstanding warrants at September 30, 2026. The outstanding warrants have a weighted average exercise price of $13.09 and expire between January 18, 2027 and July 18, 2030.

Note 6 – Net Loss per Share of Common Stock

Net Loss Per Share

Basic net loss per share of our common stock is computed by dividing our net loss by the weighted average number of shares of common stock outstanding (which includes vested RSUs) during the period. Diluted loss per share of common stock is computed by dividing our net loss by the diluted weighted average number of shares of common stock. We consider our Series A Preferred Stock, warrants, stock options and RSUs, while outstanding, to be common stock equivalents for this purpose. Diluted earnings is computed utilizing the treasury method for the warrants, stock options and RSUs. Diluted earnings with respect to the Series A Preferred Stock utilizing the if-converted method was not applicable during the periods presented as no conditions required for conversion had occurred. Incremental common stock equivalents that were anti-dilutive were excluded in calculating diluted income per share. For the three and nine months ended September 30, 2026, no common stock equivalents were included in the diluted loss per share because such inclusion would be anti-dilutive given the net loss reported for the prior year period.

We have excluded the following potentially dilutive securities from the calculation of diluted net loss per share since they would have had an anti-dilutive effect:

	September 30,	
	2026	**2025**
Shares issuable upon conversion of Series A Preferred Stock	306,574,202	-
Shares issuable upon exercise of stock options	1,183,896	112
Unvested restricted stock units	45,535	1,043
Warrants to purchase shares of common stock	1,410,066	1,602,375
Total	309,213,699	1,603,530

Note 7 – Digital Assets

Digital assets are measured at fair value on a recurring basis using quoted prices in their principal market (Level 1 inputs). We have designated a principal market based on the market we have access to that has the greatest volume and level of orderly transactions for digital assets. We reassess the principal market when facts and circumstances change, including, but not limited to, when new markets become accessible, or the volume/activity in the current principal market declines.

The following table sets forth the number of tokens, cost basis and fair value of digital assets held, as shown on the condensed consolidated balance sheet as of September 30, 2026:

	Number of Tokens	Cost basis (in thousands)	Fair value (in thousands)
CHZ tokens	26,517,000	$ 1,005	$ 431

The following table represents a reconciliation of our assets and (liabilities) related to our digital assets during the nine months ended September 30, 2026 (in thousands):

	Nine months ended September 30, 2026
Fair Value, January 1, 2026	$ 1,145
Purchases of 10,416,000 CHZ tokens	500
Cash received on sale of 11,000,000 CHZ tokens	(186)
Realized loss on sale	(159)
Unrealized loss	(869)
Fair Value, September 30, 2026	$ 431

Note 8 – Related Party Transactions

CorLyst, LLC

CorLyst, LLC (“CorLyst”) reimburses us for shared costs related to payroll and health insurance (and rent during the three and nine months ended September 30, 2025) based on actual costs incurred, which are recognized as a reduction of our general and administrative operating expenses in our condensed consolidated statements of operations. Included in our general and administrative expenses is approximately $38,000 and $24,000 of reimbursements from CorLyst during the three months ended September 30, 2026 and 2025, respectively, and $0.1 million for the nine months ended September 30, 2026 and 2025. No amounts were due at September 30, 2026 or September 30, 2025. Our President, Research and Development is the CEO of CorLyst, and CorLyst is a stockholder of the Company.

The Chiliz Group

The Chiliz Group (formerly known as ‘HX Entertainment Limited’) is the issuer of the Chiliz (CHZ) tokens. In prior periods, it purchased 305,644 shares of our common stock for a cumulative $1.4 million in net proceeds. At September 30, 2026, the Chiliz Group owned 10.9% of the shares of our common stock outstanding.

Note 9 – Segment Reporting

We manage our operations as a single segment, focused on advancing the clinical-stage BTKi program and evaluating our legacy pharmaceutical assets. As our chief operating decision maker, our CEO manages and allocates resources at a consolidated level. He assesses performance, monitors budget versus actual results, and decides how to allocate resources based on net loss that also is reported on the consolidated statement of operations and comprehensive loss as consolidated net loss.

The following table presents reportable segment profit and loss, including significant expense categories, attributable to our reportable segment for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Preclinical, clinical trial and other costs	$ 1,465	$ 1,204	$ 3,214	$ 4,543
Research and development personnel expense[(1)]	346	458	1,056	1,154
Acquired IPR&D expense	178,030	-	178,030	-
General and administrative personnel expense[(2)]	705	855	1,967	2,158
Administrative and facilities expense[(3)]	3,583	972	5,530	2,432
Other expense, net[(4)]	(972)	(52)	3	(82)
Total	$ 183,157	$ 3,437	$ 189,800	$ 10,205

(1) Research and development personnel costs include employee stock-based compensation expense of $57 and $110 for the three months ended September 30, 2026 and 2025, respectively, and $92 and $166 for the nine months ended September 30, 2026 and 2025, respectively.
(2) General and administrative personnel costs include employee stock-based compensation expense of $182 and $193 for the three months ended September 30, 2026 and 2025, respectively, and $283 and $438 for the nine months ended September 30, 2026 and 2025, respectively, and are net of reimbursements received from CorLyst, LLC.
(3) Administrative & facilities expense primarily consists of facilities expenses, office expenses, legal costs, insurance, consulting, travel, and other administrative costs.
(4) Other income, net consists of interest and dividend income, realized and unrealized losses on our digital assets, and other miscellaneous income.

Note 10 – Commitments and Contingencies

Purchase Obligations

We enter into contracts in the normal course of business with contract research organizations (CROs) and subcontractors to further develop our products. The contracts are cancelable, with varying provisions regarding termination. If we terminated a cancelable contract with a specific vendor, we would only be obligated for products or services that we received at the effective date of the termination and any applicable cancellation fees. Following the termination of our license agreement with Elion (see Note 11), we will be closing our ongoing NGC-Cap (also known as PCS6422 + Capecitabine) Phase 2 trial and expect the costs to wind down the trial to be approximately $0.2 million over the next few months. Actual costs to wind down the trial could exceed these estimates.

Note 11 – Modifications to License Agreements

Amendment of our License Agreement with Yuhan Corporation

On August 14, 2026, Yuhan Corporation executed Amendment No. 2 to our existing license agreement dated August 19, 2020, effective August 14, 2026, which extended to August 14, 2027 the deadline to dose the first patient in a Phase 2B clinical trial, Phase 3 clinical trial or other pivotal clinical trial.

Termination of our License Agreement with Elion Oncology, Inc.

On July 23, 2026, we terminated our license agreement, dated August 23, 2020 with Elion Oncology, Inc. (“Elion License Agreement”), pursuant to a settlement agreement entered into on that date (the “Settlement Agreement”). Pursuant to the Settlement Agreement, the parties agreed to settle all claims in respect of our litigation regarding the Elion License Agreement and to terminate the Elion License Agreement without further obligation of either party, with us returning the PCS6422 program to Elion. In connection with the Settlement Agreement, the parties exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program and the related litigation. As part of the Settlement Agreement, we agreed to pay Elion the sum of $0.7 million. In addition, we agreed to grant to Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity whose assets include one or more of PCS499, PCS12852, or PCS11T, if the formation or spin-out is completed within one year following the effective date of the Settlement Agreement. On August 7, 2026, the filed stipulation became effective as a final dismissal with prejudice.

Accordingly, we are terminating the Phase 2 trial of PCS6422 in advanced/metastatic breast cancer.

Note 12 – Subsequent Events

Generian Agreement

On October 12, 2026, Vidya Therapeutics Operating LLC (“Vidya Subsidiary”), a wholly owned subsidiary of the Company, entered into a Collaboration and Exclusive Option Agreement (the “Generian Agreement”) with Generian Pharmaceuticals, Inc. (“Generian”) to advance a program of orally administered inhibitors of the neonatal Fc receptor (FcRn) through nomination of a development candidate.

Under the Generian Agreement, Generian granted Vidya Subsidiary an exclusive option to obtain an exclusive, worldwide license to the related technology. Vidya Subsidiary paid a non-refundable upfront payment of $4.0 million and research and development reimbursement of $0.5 million. The Company may fund additional research and development activities intended to advance the program through development candidate nomination, if approved by the Company.

Vidya Subsidiary is not obligated to exercise the option. If exercised, Vidya Subsidiary would pay a non-refundable exercise fee, be obligated to pay clinical, regulatory and sales-based milestone payments and pay a royalty fee on future sales of the licensed asset. The option structure is intended to provide Vidya Subsidiary with the opportunity to evaluate the program’s continued development based on the results of the research and development activities conducted during the option period. We guaranteed Vidya Subsidiary’s payment obligations under the Generian Agreement.

A member of our Board also serves as a member of Generian’s Board of Directors. The Generian Agreement was reviewed and approved by our Board, with that Director recusing themselves from the deliberations and vote.

Our accounting evaluation of the Generian Agreement is ongoing, and its preliminary conclusion, which is subject to change, is that the transaction represents an asset acquisition of in-process research and development with no alternative future use. On that basis, we currently expect to record the non-refundable upfront payment as research and development expense in the fourth quarter of 2026, with the funded research costs expensed as the services are performed.

Appointment of Chief Operating Officer

On November 2, 2026, our Board approved the appointment of Gregory J. Flesher as Chief Operating Officer, effective November 4, 2026. In connection with his appointment, the Company entered into an employment agreement with Mr. Flesher which is incorporated by reference in Exhibit 10.4.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" that reflect, when made, the Company's expectations or beliefs concerning future events that involve risks and uncertainties. Forward-looking statements frequently are identified by the words "believe," "anticipate," "expect," "estimate," "intend," "project," "will be," "will continue," "will likely result," or other similar words and phrases. Similarly, statements herein that describe the Company's objectives, plans or goals also are forward-looking statements. Actual results could differ materially from those projected, implied or anticipated by the Company's forward-looking statements. Some of the factors that could cause actual results to differ include: our limited cash and history of losses; our ability to achieve profitability; our ability to obtain adequate financing to fund our business operations in the future; our ability to secure required U.S. Food and Drug or other governmental approvals for our product candidates and the breadth of the indication sought; the impact of competitive or alternative products, technologies and pricing; whether we are successful in developing and commercializing our technology, including through licensing; the adequacy of protections afforded to us and/or our licensors by the anticipated patents that we own or license and the cost to us of maintaining, enforcing and defending those patents; our and our licensors' ability to protect non-patented intellectual property rights; our exposure to and ability to defend third-party claims and challenges to our and our licensors' anticipated patents and other intellectual property rights; our ability to remain listed on the Nasdaq Capital Market; and our ability to continue as a going concern. For a discussion of these and all other known risks and uncertainties that could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" herein, in the "Risk Factors' included in the Company's Current Report on Form 8-K filed on October 5, 2026, and in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, which is available on the SEC's website at www.sec.gov. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update this Quarterly Report on Form 10-Q to reflect events or circumstances after the date hereof.

References to the "Company," "we," "us" or "our" refer to the operations of Processa Pharmaceuticals, Inc. and its direct and indirect subsidiaries for the periods described herein.

Overview

We are a clinical-stage pharmaceutical company advancing differentiated therapeutic programs for immunological and inflammatory diseases. In July 2026, we acquired Vidya Therapeutics, Inc. ("Vidya"), a clinical-stage biotechnology company developing VT-7208, a Bruton's tyrosine kinase inhibitor ("BTKi") therapy for immune-mediated diseases with an initial focus on food allergy, chronic spontaneous urticaria ("CSU") and relapsing multiple sclerosis ("RMS"). We also intend to explore VT-7208 in additional immune-mediated diseases. Our second program is a preclinical oral neonatal Fc receptor (FcRn) antagonist being explored for treatment of immune-mediated diseases. We are also continuing the development of our legacy pharmaceutical assets, including PCS499, PCS12852 and PCS11T, while evaluating strategic opportunities designed to maximize their clinical and long-term value.

Recent Developments

Vidya Acquisition

On July 28, 2026, we acquired Vidya, which brought Vidya's lead asset VT-7208 into our pipeline. In connection with our acquisition of Vidya, we received $200.0 million in gross proceeds from a private placement financing of shares of our non-voting convertible preferred stock (the "2026 Private Placement"). We intend to use the net proceeds of $187.1 million from the 2026 Private Placement to fund operations into the second half of 2029 and through key clinical milestones, including top-line data from Phase 2 proof-of-concept clinical trials for food allergy, CSU and RMS.

Elion Settlement Agreement

On July 23, 2026, we entered into a settlement agreement (the "Settlement Agreement") with Elion Oncology, Inc. ("Elion") to resolve all claims arising from the parties' litigation concerning the license agreement dated August 23, 2020, relating to the commercialization of PCS6422 (the "Elion License Agreement"). Under the Settlement Agreement, the Elion License Agreement was terminated, the PCS6422 program was returned to Elion, and the parties exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program, and the related litigation. As a result of the settlement and the return of the PCS6422 program to Elion, we are terminating the Phase 2 clinical trial of PCS6422 in advanced or metastatic breast cancer. On August 7, 2026, the stipulation of dismissal became effective, resulting in the dismissal of the litigation with prejudice.

In connection with the settlement, we paid Elion $0.7 million. We also agreed to grant Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity whose assets include one or more of PCS499, PCS12852, or PCS11T, provided that the formation or spin-out of such entity is completed within one year following the effective date of the Settlement Agreement.

2026 Fundraising

During the nine months ended September 30, 2026, we sold a cumulative 219,491 shares of our common stock to certain investors in private placement transactions and through our ATM Offering for a total of $0.6 million in net proceeds. Concurrent with our acquisition of Vidya, we entered into a definitive agreement for the 2026 Private Placement to raise $200.0 million in gross proceeds, which we expect to use to support the advancement of VT-7208 through multiple clinical milestones, including data from a Phase 2 proof-of-concept clinical trial in food allergy anticipated in the second half of 2027, data from a Phase 2 proof-of-concept clinical trial in CSU anticipated in the first half of 2028, and data from a Phase 2 proof-of-concept clinical trial in RMS anticipated in the second half of 2028.

Our Drug Pipeline

Compound	Indication	Phase 1	Phase 2	Phase 3	Anticipated Next Milestones
VT-7208 (BTKi)	Food Allergy				Phase 2 initiation H2'26 Phase 2 PoC data H2'27
	CSU				Phase 2 initiation H2'26 Phase 2 PoC data H1'28
	MS				Phase 2 initiation H1'27 Phase 2 PoC data H2'28

We recently announced U.S. Food and Drug Administration clearance of the investigational new drug application for the planned Phase 2 clinical trial of VT-7208 in CSU. In addition to advancing the clinical-stage BTKi program in multiple indications, we have entered into a research collaboration and exclusive option agreement with Generian Pharmaceuticals, Inc. to advance a preclinical oral neonatal Fc receptor (FcRn) antagonist program. We are also evaluating the future development of our legacy pharmaceutical assets, including PCS499 for the treatment of primary glomerular disease, PCS12852 for the treatment of gastroparesis and constipation disorders, and PCS11T for the treatment of lung, pancreatic, ovarian, colorectal, gastric, cervical and other cancers, while evaluating strategic opportunities designed to maximize their clinical and long-term value.

Results of Operations

Comparison of the three and nine months ended September 30, 2026 and 2025

The following table summarizes our net loss during the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating Expenses				
Research and development expenses	$ 1,811	$ 1,662	$ 4,270	$ 5,697
Acquired in-process research and development expense	178,030	-	178,030	-
General and administrative expenses	4,288	1,827	7,497	4,590
Operating Loss	(184,129)	(3,489)	(189,797)	(10,287)
Other Income (Expense), net				
Unrealized loss on digital assets	(41)	-	(869)	-
Realized loss on digital assets	-	-	(159)	-
Other income	-	6	15	14
Interest income, net	1,013	46	1,010	68
Total other income (expense)	972	52	(3)	82
Net Loss	(183,157)	(3,437)	(189,800)	(10,205)
Other comprehensive loss, net of tax	(20)	-	(20)	-
Comprehensive loss	$ (183,177)	$ (3,437)	$ (189,820)	$ (10,205)

Revenues

We do not currently have any revenue under contract or any immediate sales prospects.

Research and Development Expenses

Our research and development costs are expensed as incurred. Research and development expenses include (i) program and testing related expenses including external consulting and professional fees related to the product testing and our development activities and (ii) internal research and development staff salaries and other payroll costs including stock-based compensation, payroll taxes and employee benefits.

Costs for the three and nine months ended September 30, 2026 and 2025 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Preclinical, clinical trial and other costs	$ 1,465	$ 1,204	$ 3,214	$ 4,543
Research and development salaries and benefits	346	458	1,056	1,154
Total	$ 1,811	$ 1,662	$ 4,270	$ 5,697

The increase in overall research and development expenses was primarily due to the $0.9 million of research and development expenses incurred by Vidya during the three and nine months ended September 30, 2026. During the three months ended September 30, 2026, the increase was offset by a decrease of $0.6 million in clinical trial costs as we terminated the Phase 2 clinical trial of NGC-Cap.

During the nine months ended September 30, 2026, we experienced a decrease in overall research and development expenses, primarily due to a decrease in preclinical, clinical trial, and other costs of $2.2 million as we had put a hold on our Phase 2 clinical trial of NGC-Cap while we conducted interim analysis and eventually terminated the clinical trial.

Our clinical trial cost accruals are based on estimates of patient enrollment and related costs at clinical investigator sites, as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf.

We estimate preclinical and clinical trial expenses based on the services performed, pursuant to contracts with research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. In accruing service fees, we estimate the time period over which services will be performed and the level of patient enrollment and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses and expensed when the services are rendered.

General and Administrative Expenses

The increase in overall general and administrative expenses was primarily due to the $1.6 million of general and administrative expenses incurred by Vidya and the $0.7 million settlement payment to Elion during the three and nine months ended September 30, 2026.

Our general and administrative expenses for the three months ended September 30, 2026 increased by approximately $2.5 million to $4.3 million from $1.8 million for the three months ended September 30, 2025. In addition to the costs incurred by Vidya and the settlement payment to Elion, we experienced increases in professional fees of approximately $0.5 million. The increases were offset by decreases in investment management fees of $0.2 million related to our cryptocurrency wallet and salaries and payroll-related expenses of $0.1 million for one-time bonuses, both of which were paid in 2025.

Our general and administrative expenses for the nine months ended September 30, 2026 increased by approximately $2.9 million to $7.5 million from $4.6 million for the nine months ended September 30, 2025. In addition to the costs incurred by Vidya and the settlement payment to Elion, we experienced increases in professional fees of approximately $0.9 million and insurance expense of approximately $0.2 million. The increases were offset by decreases in employee stock-based expenses of $0.2 million; investment management fees of $0.1 million; and office, rent and other miscellaneous expenses of $0.2 million.

Other Income (Expense)

Other income (expense) for the three and nine months ended September 30, 2026 and 2025 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Unrealized loss on digital assets	$ (41)	$ -	$ (869)	$ -
Realized loss on digital assets	-	-	(159)	-
Other income	-	6	15	14
Interest income, net	1,013	46	1,010	68
Total other income (expense)	$ 972	$ 52	$ (3)	$ 82

Our other income for the three and nine months ended September 30, 2026 increased due to interest earned on funds from the 2026 Private Placement.

Income Tax Benefit

We did not recognize any income tax benefit for the three and nine months ended September 30, 2026 or 2025.

Cash Flows

The following table sets forth our sources and uses of cash and cash equivalents for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine months ended September 30,	
	2026	2025
Net cash (used in) provided by:		
Operating activities	$ (10,763)	$ (8,485)
Investing activities	(2,212)	-
Financing activities	187,693	13,602
Effect of exchange rate changes	(50)	-
Net increase in cash	$ 174,668	$ 5,117

Net cash used in operating activities

We used net cash in our operating activities of $10.8 million and $8.5 million during the nine months ended September 30, 2026 and 2025, respectively. The increase in cash used in operating activities during the nine months ended September 30, 2026 compared to the same period in 2025 was primarily related to the $2.5 million in expenses incurred by Vidya for its operations during the nine months ended September 30, 2026.

As we advance VT-7208 through three Phase 2 proof-of-concept clinical trials and explore additional immune-mediated diseases, and evaluate the preclinical oral FcRn antagonist and legacy product candidates in our portfolio, we anticipate our research and development efforts and ongoing general and administrative costs will continue to generate negative cash flows from operating activities for the foreseeable future. We anticipate our clinical trial costs will increase in the second half of 2026 when compared to prior periods as we advance three planned Phase 2 clinical trials of VT-7208, since activities in 2025 were primarily related to the completion of our Phase 1B trial and setup of our NGC-Cap Phase 2 trial.

Net cash used in investing activities

We used $1.9 million for fees incurred in connection with the asset acquisition, $0.5 million in investing activities to purchase digital assets and received $0.2 million for the sale of digital assets during the nine months ended September 30, 2026. We did not use any cash in investing activities during the same period in 2025.

Net cash provided by financing activities

During the nine months ended September 30, 2026, we received $187.1 million in net proceeds from the issuance of Series A Preferred Stock, and sold a cumulative 219,491 shares of our common stock to certain investors in private placement transactions and through our ATM Offering for a total of $0.6 million in net proceeds.

During the nine months ended September 30, 2025, we received net proceeds of $12.9 million in public offerings completed in January and June 2025 from selling a cumulative 1,016,232 shares of common stock and pre-funded warrants to purchase up to 828,388 shares of common stock. The public offering in January also included accompanying Series A Warrants to purchase up to 322,027 shares of our common stock and Series B Warrants to purchase up to 161,014 shares of common stock and the public offering in June included accompanying warrants to purchase up to 1,120,000 shares of common stock. We also received $0.7 million from the exercise of warrants to purchase 116,497 shares of common stock sold in our June offering.

Liquidity

As of September 30, 2026, our principal sources of liquidity consisted of cash and cash equivalents of $180.2 million. We believe our current available cash and cash equivalents will be sufficient to fund our operations for at least the next 12 months from the date of issuance of these financial statements. As of September 30, 2026, our cash and cash equivalents were invested primarily in cash deposits and cash equivalent investments.

The Series A Preferred Stock are convertible into shares of common stock, subject to receiving stockholder approval of the issuance of shares of common stock upon conversion of Series A Preferred Stock and exercise of the Assumed Options (see Note 2 for additional information on the planned proposals for the stockholder meeting). Under the terms of the Certificate of Designation of Preferences, Rights and Limitations of the Series A Preferred Stock (the "Certificate of Designation"), if we fail to deliver to the holder of the Series A Preferred Stock shares of our common stock underlying such shares of Series A Preferred Stock at any time nine months after the initial issuance of the Series A Preferred Stock, holders of the Series A Preferred Stock are entitled to require us to make cash payments by wire transfer of immediately available funds equal to the Fair Value (as defined in the Certificate of Designation) of such undelivered shares, subject to the applicable conversion-notice and delivery requirements, exceptions and availability of legally available funds. As a result, we concluded that the proceeds received from the private placement financing cannot be relied upon to mitigate the conditions that raised substantial doubt because the availability of those proceeds is subject to conditions that are not entirely within our control. Our plan to address this potential cash-settlement obligation is to obtain the requisite stockholder approval at a meeting expected to take place in the first quarter of 2027 and thereafter complete the conversion of the Series A Preferred Stock and delivery of the underlying common stock, subject to applicable beneficial ownership limitations. Accordingly, we concluded that substantial doubt about our ability to continue as a going concern continues to exist within one year after the date these financial statements are available to be issued.

We have incurred losses since inception, currently devoting substantially all our efforts toward research and development of our product candidates, including conducting clinical trials and providing general and administrative support for these operations, and have an accumulated deficit of $290.6 million at September 30, 2026. During the nine months ended September 30, 2026, we generated a net loss of $189.8 million. To date, none of our drug candidates have been approved for sale, and therefore we have not generated any product revenue and do not expect positive cash flow from operations in the foreseeable future. We will continue to be dependent upon equity and/or debt financing until we are able to generate positive cash flows from our operations.

We plan to raise additional funds in the future through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements, but will only do so if the terms are acceptable to us. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation, warrants or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through future collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development, future commercialization efforts, or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

During the nine months ended September 30, 2026, there have been no significant changes to the contractual obligations reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025.

Off Balance Sheet Arrangements

At September 30, 2026, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our most recent Annual Report on Form 10-K have the greatest potential impact on our financial statements, so we consider these to be our critical accounting policies. Actual results could differ from the estimates we use in applying our critical accounting policies. We are not currently aware of any reasonably likely events or circumstances that would result in materially different amounts being reported.

We acquired in-process research and development ("IPR&D") in the Vidya Acquisition that was recorded at the fair value of the consideration given. This represents research and development projects which were in process, but not yet completed, and which we may advance following the Vidya Acquisition, including the development of VT-7208. The fair value of IPR&D projects acquired in an asset acquisition with no alternative future use are charged to expense on the acquisition date. Substantially all of the fair value of the gross assets acquired was concentrated in the acquired IPR&D, a single identifiable asset, and the transaction therefore passed the screen test under ASC 805. Accordingly, the acquired set of assets did not meet the definition of a business. Additionally, the acquired assets did not include the outputs or meaningful processes necessary to be considered a business under ASC 805. The IPR&D costs were immediately expensed.

Recently Issued Accounting Pronouncements

We have evaluated recently issued accounting pronouncements and determined that there is no material impact on our financial position or results of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Item 3 is not applicable to us as a smaller reporting company and has been omitted.

Item 4. Controls and Procedures

At September 30, 2026, management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on the evaluation of its disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at September 30, 2026 to provide reasonable assurance that information required to be disclosed in our reports under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, as appropriate, to allow timely decisions regarding required disclosure. Our assessment of internal control over financial reporting did not include the internal control over financial reporting for Vidya which was acquired in the third quarter of 2026. Vidya's total assets and expenses represent 2.1% and 1.3%, respectively, of our consolidated total assets and expenses as of and for the nine months ended September 30, 2026. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting. In connection with the Vidya Acquisition, we have begun the process of integrating Vidya's financial processes, systems, and personnel into our system of internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

On July 23, 2026, we entered into a settlement agreement (the "Settlement Agreement") with Elion Oncology, Inc. ("Elion") to resolve all claims arising from the parties' litigation concerning the license agreement dated August 23, 2020, relating to the commercialization of PCS6422 (the "Elion License Agreement"). Under the Settlement Agreement, the Elion License Agreement was terminated, the PCS6422 program was returned to Elion, and the parties exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program, and the related litigation. In connection with the settlement, we paid Elion $0.7 million towards its attorneys' fees and other out-of-pocket costs. We also agreed to grant Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity whose assets include one or more of PCS499, PCS12852, or PCS11T, provided that the formation or spin-out of such entity is completed within one year following the effective date of the Settlement Agreement. As a result of the settlement and the return of the PCS6422 program to Elion, we are closing our ongoing Phase 2 clinical trial of PCS6422 in advanced or metastatic breast cancer. On August 7, 2026, the stipulation of dismissal became effective, resulting in the dismissal of the litigation with prejudice.

On December 3, 2024, Jason Assad and Marc Gyimesi, two of the investors in our February 2021 private offering, filed a lawsuit that has been assigned to the Commercial Division of the Supreme Court of the State of New York, New York County alleging fraud and negligent misrepresentation in connection therewith regarding alleged company communication and statements and are seeking monetary damages. In addition to being an investor, Mr. Assad was a former investor relations and communications consultant to the Company from September 1, 2021 through June 30, 2024. On April 25, 2025, the Company filed a motion to dismiss the complaint in its entirety. The motion was decided in September 2025. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). The court also dismissed all claims against Patrick Lin and George Ng. Processa's and David Young's answer was submitted during October 2025. In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against Processa and David Young based on the same factual allegations. Processa's and David Young's response to the amended complaint (a motion to dismiss) was submitted on March 2, 2026 and is still pending before the Court. At the Court's request, we also filed a non-substantive submission concerning oral argument. We expect to draft and file a motion for summary judgement in the fourth quarter. In the meantime, the discovery and deposition phases of the matter are ongoing.

We intend to vigorously defend ourselves in these lawsuits and cannot at this time predict the likely outcome of any litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how these matters or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information herein. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

SUMMARY OF RISK FACTORS

The risk factors summarized below could materially harm our business, operating results, and/or financial condition, impair our future prospects, and/or cause the price of our common stock to decline. These risks are discussed more fully below. Material risks that may affect our business, financial condition, results of operations, and trading price of our common stock include the following:

- We have a limited operating history and have had a history of significant losses since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.
- We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts. Our development efforts are in the early stages. If we are unable to advance VT-7208 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on the success of VT-7208. VT-7208 will require additional clinical and manufacturing development before we may be able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.
- If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- We will depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.
- We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.
- If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.
- We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

- Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

- There is no guarantee that the Merger will increase stockholder value.

- Pursuant to the terms of the Merger, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

- We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations (including clinical trials); reputational harm; loss of revenue or profits; and other adverse business consequences. The failure to successfully integrate the businesses of the Company and Vidya in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have a history of significant losses since our inception. We may incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage pharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess the future viability of our business prospects. Our operations to date have been limited to business planning, including the Merger, organizing and staffing our company, raising capital, identifying potential product candidates, conducting clinical trials and preclinical studies for our development programs, entering into licensing agreements, establishing and enhancing our intellectual property portfolio, and providing general and administrative support for these operations.

We have a history of significant net losses since our inception. Our net loss was $189.8 million and $10.2 million for the nine months ended September 30, 2026 and 2025, respectively, and $13.6 million and $11.9 million for the years ended December 31, 2025 and 2024, respectively. As of September 30, 2026 and as of December 31, 2025, we had an accumulated deficit of $290.6 million and $100.8 million, respectively. We have funded our operations to date primarily with proceeds from the sale of our equity securities.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our product candidates, and are devoting substantially all of our financial resources and efforts to the research and development of VT-7208. Investment in clinical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable.

We expect that it will take at least several years until any of our product candidates receive marketing approval and are commercialized, and we may never be successful in obtaining marketing approval and commercializing product candidates. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. Achievement will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining regulatory approval, manufacturing, marketing and selling any products for which we may obtain regulatory approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with the development and commercialization of therapeutic product candidates, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve and maintain profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase and profitability could be further delayed.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

Our operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture our product candidates at commercial scale or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. We may encounter unforeseen expenses, difficulties, complications, and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty, particularly with respect to the Merger. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer.

We will need substantial additional funding to complete the development of our product candidates. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, we have used substantial amounts of capital to fund the development of our product candidates and operations. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as our product candidates enter and advance through preclinical studies and clinical trials. We will require substantial additional funding to meet our financial needs and to pursue our business objectives. We will require significant additional capital to, among other things:

- complete our ongoing and planned clinical trials, preclinical studies and Investigational New Drug Application (IND)-enabling activities;
- initiate, enroll, and complete additional clinical trials for our product candidates;
- seek and obtain regulatory approvals for our product candidates;
- build and maintain our manufacturing capabilities or enter into third-party manufacturing arrangements;
- expand and protect our intellectual property portfolio; and
- fund our general and administrative operations.

In addition, if we obtain marketing approval for any of our product candidates, we will incur significant commercialization expenses related to marketing, sales, administration and manufacturing and distribution.

Failure to raise capital as and when needed would have a negative impact on our financial condition and ability to develop our product candidates. Furthermore, we cannot be certain that additional funding will be available on acceptable terms. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives, and any of our current or future license agreements may be terminated if we are unable to meet the payment or other obligations under the agreements.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, license and collaboration agreements and research grants. If we raise capital through securities offerings, such sales are likely to result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity, warrants to purchase equity, and/or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. In addition, we could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. If we raise funds through research grants, we may be subject to certain requirements, which may limit our ability to use the funds or require us to share information from our research and development. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our stockholders, and may cause the market price of our common stock to decline.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish some rights to our technologies or our product candidates on terms that are not favorable to us. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved. If we are unable to raise capital when needed or on attractive terms, we could be forced to further delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Our business could be adversely affected by economic downturns, inflation, increases in interest rates, natural disasters, public health crises such as pandemics, political crises, geopolitical events, or other macroeconomic conditions, which have in the past and may in the future negatively impact our business and financial performance.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including, among other things, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, supply chain shortages, increases in inflation rates, higher interest rates and uncertainty about economic stability, due to reasons including, among other things, geopolitical conflicts, political changes and trends such as protectionism, economic nationalism resulting in government actions impacting international trade agreements or imposing trade restrictions such as tariffs and retaliatory counter measures.

A widespread public health crisis such as a pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could negatively affect our liquidity. In addition, a recession or market correction resulting from the effects of public health crises could materially affect our business and the value of our common stock. It may have further negative impacts, such as (a) a global or U.S. recession or other economic crisis; (b) credit and capital markets volatility (and access to these markets, including by our suppliers and customers); (c) manufacturing supply disruption due to travel restrictions or other government actions; (d) disruptions in raw material supply, our manufacturing operations, or in our distribution and supply chain; and (e) our ability to conduct planned clinical trials and commercialization activities. The ultimate impact of a public health crisis is highly uncertain.

Fluctuating interest rates, coupled with reduced government spending and volatility in financial markets, may increase economic uncertainty and affect consumer spending. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and employee benefit costs.

Vidya conducts certain research and development operations through a wholly-owned Australian subsidiary and benefits from the Australian Government's Research and Development Tax Incentive program. A reduction in, or loss of eligibility for, these incentives from the Australian government could increase our net cost of conducting research and development.

We have historically received cash incentives through the Australian Government's Research and Development Tax Incentive program, under which the Australian Government currently provides a refundable tax offset, payable as a cash incentive, for certain eligible approved research and development expenditures by Australian entities. Entitlement to tax offsets under the Research and Development Tax Incentive for eligible research and development purposes is based on an annual application to the Australian Government. For overseas activities with a significant scientific link to Australian activities, the expenditure in Australia must exceed the expected overseas expenditure to be eligible.

If our research and development expenditures are deemed "ineligible," our incentives would decrease and the net cost of conducting research and development would increase. In addition, our prior claims under the program remain subject to review by the Australian Taxation Office for up to four years after receipt. If any previously claimed expenditures are later determined to be ineligible, we could be required to repay some or all of the related incentive payments. The Australian Government may modify the requirements of, reduce the amounts of the tax offset entitlement under, or discontinue the Research and Development Tax Incentive program. If the Research and Development Tax Incentive program were discontinued, or if the tax incentive rate were reduced, it would negatively affect the size of future refundable tax offsets and our future cash flows. If our subsidiary loses its ability to operate in Australia, or if we are ineligible or unable to receive the research and development incentive payment, or the Australian government significantly reduces or eliminates the incentive program, our business and results of operation may be adversely affected.

Risks Related to the Development of our Product Candidates

Our development efforts are in the early stages. If we are unable to advance VT-7208 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

There is no assurance that any clinical trials of VT-7208, or any other product candidates we may develop will be successful or will generate positive clinical data and we may not receive marketing approval from the FDA or other regulatory agencies for any such product candidate. VT-7208 is in the early stage of our development efforts, and if it, or any product candidate that we may develop, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. We have completed a Phase 1 clinical trial of VT-7208 in healthy volunteers and are planning Phase 2 clinical trials of VT-7208 in food allergy and chronic spontaneous urticaria (CSU) expected to initiate in the second half of 2026, and a Phase 2 clinical trial of VT-7208 in relapsing multiple sclerosis (MS) expected to initiate in the first half of 2027.

Biopharmaceutical development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates will prevent us from commercializing and marketing our product candidates. The success in the development of our product candidates will depend on many factors, including:

- initiating, enrolling, and completing clinical trials;
- submission of INDs for and receipt of allowance to proceed with our clinical trials or other future clinical trials;
- completing preclinical studies;
- obtaining positive results from our preclinical studies and clinical trials that support a demonstration of efficacy, safety, and durability of effect for our product candidates;

- receiving approvals for commercialization of our product candidates from applicable regulatory authorities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- manufacturing our product candidates at an acceptable cost and quality; and
- maintaining and growing an organization of scientists, medical professionals and business people who can develop and commercialize our product candidates and technology.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing and the regulatory submission process. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, or any other factors impacting the successful development of biopharmaceutical products, we could experience significant delays or an inability to successfully develop our product candidates, which could materially harm our business.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for VT-v7208 or any other product candidate we may develop, our business will be substantially harmed.

We do not have any products that have gained regulatory approval. Our business is substantially dependent on our ability to obtain and maintain regulatory approval for our development products, in particular VT-7208. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA. Before obtaining regulatory approvals for the commercial sale of any product candidate for a particular indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies that the product candidate is safe and effective for that indication and that the manufacturing facilities, processes and controls are adequate to ensure sufficient product quality and control with respect to such product candidate. Prior to seeking approval for any of our product candidates, we will need to confer with the FDA and other regulatory authorities regarding the design of our clinical trials, the type and amount of clinical data necessary, the Chemistry, Manufacturing and Controls (CMC) requirements to seek and gain approval for our product candidates.

The time required to obtain approval by the FDA and other regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or other comparable regulatory authorities for many reasons, including:

- disagreement with the design, protocol or conduct of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;

- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a New Drug Application (NDA) or other submission or to obtain regulatory approval;

- failure to obtain approval of the manufacturing processes, or failure to obtain such approvals with respect to our facilities or the facilities of our contract manufacturing vendors;

- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval;

- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;

- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;

- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy current good manufacturing practice (cGMP) requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;

- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;

- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or

- lack of adequate funding to complete a clinical trial in a manner that is satisfactory to the applicable regulatory authority.

Many of these risks are beyond our control, including the risks related to clinical development. If we are unable to develop, receive regulatory approval for, or successfully commercialize our product candidates, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

The FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data to support approval, including data that would require us to perform additional clinical trials or modify our manufacturing processes, controls, specifications, labeling, instructions or packaging, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. Further, if we change the primary or secondary endpoints in any of our clinical trials, either by our own choice or at the request of the FDA or a comparable regulatory authority, our development plans could be delayed, our costs could increase and our business could be materially harmed. If we change our manufacturing processes, we may be required to conduct additional clinical trials or other studies, which also could delay or prevent approval of our product candidates. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer indications than we request (including failing to approve the most commercially promising indications), may limit indications, may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing commitments, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA or other comparable regulatory authorities in other jurisdictions, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product candidate or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our business is highly dependent on the success of VT-7208. VT-7208 will require additional clinical and manufacturing development before we are able to seek regulatory approval for and launch a product commercially and we may not be successful in our efforts.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We are devoting substantially all our resources to the development of VT-7208 across our three initial target indications of food allergy, CSU and relapsing MS. Our existing clinical data for VT-7208 is derived from a completed Phase 1 clinical trial in healthy volunteers involving single ascending dose (SAD) and multiple ascending dose (MAD) cohorts with 24 subjects. We are planning Phase 2 clinical trials in food allergy, CSU and relapsing MS. If VT-7208, across the various target indications, encounters safety or efficacy problems, development delays, regulatory issues or other problems, our development plans and forecasted timelines and business could be significantly harmed. Because substantially all of our resources are concentrated on a single product candidate, any failure or significant delay in VT-7208's development would have a disproportionate impact on our business, financial condition and prospects, and we do not have other clinical-stage programs that could offset such a setback.

We cannot provide you with any assurance that we will be able to successfully advance VT-7208 or any additional product candidates through the development process in any particular target indication. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our product candidates may not succeed in preclinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects, or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our development program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which could have a material adverse effect on our business and could potentially cause us to cease operations.

If we do not successfully develop and commercialize product candidates or collaborate with others to do so, we will not be able to obtain product revenue in future periods, which could significantly harm our financial position and adversely affect the trading price of our common stock.

If the clinical trials of any of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or other comparable regulatory authorities, or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, of sufficient purity and effective for use in each target indication, and failures can occur at any stage of testing. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication. A failure of one or more clinical trials can occur at any stage of testing. Any side effects or patient deaths could affect the development of our product candidates, even if deemed to not be drug related.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

We may experience numerous unforeseen events prior to, during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize any of our product candidates, including:

- the FDA or other comparable regulatory authority may disagree as to the number, design or implementation of our clinical trials, or may not interpret the results from clinical trials as we do;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results;
- we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or abandon our product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, participants may drop out of these clinical trials at a higher rate than we anticipate or we may fail to recruit suitable patients to participate in a trial;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators may issue a clinical hold, or regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or other comparable regulatory authorities may fail to approve our manufacturing processes or facilities, or the facilities of our contract manufacturing vendors;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- deficiencies in our CMC package, including inadequate characterization of the drug substance or drug product, insufficient control strategy, incomplete validation of manufacturing processes or analytical methods, or unresolved comparability, impurity, stability or specification issues, may delay or prevent approval;

- we may be unable to demonstrate that our manufacturing processes can be consistently scaled, validated and controlled to produce product candidates that meet applicable identity, strength, quality, purity and potency requirements;

- our analytical methods, release testing, reference standards or stability data may be insufficient to support product specifications, shelf life, storage conditions or commercial manufacturing approval;

- manufacturing facilities operated by us or our third-party manufacturers may fail to satisfy cGMP requirements or may be subject to inspectional observations, warning letters, import alerts or other regulatory actions that could delay or prevent approval;

- changes in raw materials, suppliers, manufacturing sites, equipment, processes or specifications may require additional comparability, validation or bridging data and could result in delay in regulatory review or approval;

- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the clinical trials; and

- the approval policies or regulations of the FDA or other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

To the extent that the results of the trials are not satisfactory for the FDA or regulatory authorities in other countries or jurisdictions to approve our NDAs or other comparable applications, the commercialization of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Clinical trials are difficult to design and implement, can be lengthy and expensive, involve uncertain outcomes and may not ultimately be successful.

It is impossible to predict when or if any of our current or future product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Human clinical trials are expensive, can take many years to complete, and are difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. As an organization, we have limited experience designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. There is a high failure rate for autoimmune disease product candidates proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Negative outcomes or data integrity failures by competitors in the autoimmune disease space could adversely affect our business, reputation, and the regulatory and commercial environment in which we operate.

The clinical and commercial success of VT-7208 may be influenced not only by our own data and results, but also by the outcomes and perceived integrity of data generated by competitors operating in the same therapeutic area. If a competitor's product or product candidate is withdrawn from the market, subject to a safety recall, or associated with serious adverse events, whether in clinical trials or following regulatory approval, patients, physicians, payers, and the broader medical community may develop a generalized skepticism or loss of confidence in the underlying treatment modality or target mechanism. This loss of confidence could reduce patient enrollment in our clinical trials, dampen physician adoption of our products, or cause payers to impose more restrictive coverage and reimbursement policies, regardless of whether our products share the specific deficiencies identified in the competitor's product.

In particular, hepatoxicity seen in the Bruton's tyrosine kinase (BTK) inhibitor class could adversely affect perceptions of VT-7208. Evobrutinib and fenebrutinib were each placed on partial clinical hold following cases of liver-enzyme elevation, and the development of tolebrutinib, despite receiving approval from the European Medicines Agency (EMA) in progressive MS, has likewise been impacted by hepatic safety findings. These prior hepatic safety events may cause regulators, physicians, patients and investors to apply heightened scrutiny to VT-7208. There can be no assurance that VT-7208 will not encounter similar safety issues in larger or longer clinical trials or that the class-wide perception of hepatic risk will not impair our ability to enroll patients, attract investigators, obtain regulatory approval or achieve commercial acceptance. If VT-7208 is unable to differentiate itself from the hepatotoxicity profile associated with other members of the BTK inhibitor class, or if additional adverse hepatic events are reported by competitors developing BTK inhibitors for autoimmune indications, our business, financial condition, results of operations and prospects could be materially adversely affected.

We have no control over the research, development, manufacturing, or commercial practices of our competitors in the autoimmune disease space, and we cannot predict whether their data or products will meet the standards expected by regulators, the medical community, or the public. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, we are currently focusing the majority of our efforts on the development of VT-7208, and specifically for the clinical indications of food allergy, CSU and relapsing MS. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

Success in preclinical studies or clinical trials may not be predictive of results in future clinical trials.

Results from preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials are not necessarily predictive of final results. We do not know whether our candidates will be effective for the intended indications or safe in humans. Our product candidates may fail to show the desired safety and efficacy in preclinical or clinical development despite positive results observed in early preclinical studies or having successfully advanced through initial clinical trials. Any failure to establish sufficient efficacy and safety could cause us to abandon clinical development of our product candidates. Further, our clinical trials to date have involved small patient populations. Because of the small sample sizes, the results of these trials may not be indicative of results of future clinical trials.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patients are enrolled and additional data become available and are subject to audit and verification procedures that could result in material changes in the final data.

We expect to publish from time to time interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Since the number of patients that have been and will be dosed in our completed Phase 1 clinical trial of VT-7208 is small, the results from such clinical trial may be less reliable than or may not be predictive of results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for VT-7208.

The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the characteristics of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. Our completed Phase 1 clinical trial of VT-7208 enrolled 24 healthy volunteers. The small number of subjects enrolled in this trial limits the statistical power of our results and increases the potential for any individual subject outcome to disproportionately influence our overall findings. As a result, there may be less certainty that VT-7208 would achieve a statistically significant effect in any future clinical trials in patient populations. Further, there can be no assurance that the results observed in our Phase 1 trial will be replicated in patient populations across these indications. The planned Phase 2 trials will enroll patient populations with distinct disease characteristics, and VT-7208 may not demonstrate the safety, tolerability, or efficacy profile necessary to support further clinical development in one or more of these indications. If those results are not indicative of data that would be generated in larger clinical trials, our assumptions in support of our clinical development activities may prove to be inaccurate and the FDA or other comparable regulatory authorities may require us to conduct additional and larger clinical trials than we currently plan.

If we conduct any future clinical trials of VT-7208 or our other product candidates, we may not achieve a positive or statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on prior results from our completed or ongoing trials. Such failure could hinder our efforts to obtain regulatory approval for VT-7208 or our other product candidates.

The comparisons we present regarding VT-7208's safety and efficacy profile relative to other BTK inhibitors are subject to significant limitations and may not be predictive of VT-7208's relative performance in future controlled studies.

Herein, and in our other public communications, we present data comparing VT-7208's pharmacokinetics, emerging preclinical profile and predicted drug-induced liver injury risk score to other BTK inhibitors, including tolebrutinib and remibrutinib. These comparisons are derived from preclinical studies of VT-7208 and conducted against these other BTK inhibitors. Outside of the preclinical head-to-head studies, no head-to-head clinical trials have been conducted comparing VT-7208 to any other BTK inhibitor, and cross-trial comparisons are inherently limited and may not accurately reflect the relative safety or efficacy of the agents being compared. The results of any preclinical head-to-head studies may not be predictive of relative CNS exposure in humans. Any published data from the clinical trials of these other BTK inhibitors are from trials conducted at different times, with differences in trial design, patient populations, disease settings, dosing regimens, endpoints, sample sizes, follow-up periods, and adverse event grading criteria from the clinical trials for VT-7208. Physicians, patients, investors, and regulatory authorities may draw conclusions from cross-trial comparisons that are not supported by the underlying data or may discount VT-7208's potential based on the inherent limitations of such comparisons. In particular, comparisons based on published results from a competitor may become outdated if such competitor generates additional clinical data. If VT-7208's clinical profile does not compare as favorably to other BTK inhibitors as our preclinical analyses suggest, or if our hepatotoxicity differentiation claims are not borne out in clinical studies, the commercial prospects and perceived differentiation of VT-7208 could be materially diminished.

We depend on timely enrollment of patients in our clinical trials for our product candidates. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the number of patients with the disease or condition being studied;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- clinicians' and patients' perceptions as to any risks associated with our competitors' product candidates;
- the size and nature of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion of their treatment;

- factors we may not be able to control, such as pandemics, that may limit patients, principal investigators or staff or clinical sites available;
- delays in activating clinical trial sites, including delays related to site contracting, budgeting, institutional review board or ethics committee approvals, training or initiation activities;
- high screen failure rates, including as a result of narrow eligibility criteria, required diagnostic confirmation or other protocol-specific requirements;
- competition from approved therapies, standard-of-care alternatives or other treatment options that may reduce patients' willingness to enroll in our clinical trials;
- the burden on patients participating in our clinical trials, including visit frequency, travel requirements, monitoring obligations, procedures, follow-up requirements or other protocol-related demands;
- the availability of specialized testing, biomarkers or diagnostic tools needed to identify or confirm eligible patients;
- our ability to enroll a sufficiently diverse and representative patient populations across demographics, disease characteristics or geographies to support regulatory review;
- patient retention, protocol adherence and timely completion of trial visits and procedures, including missed visits, noncompliance or withdrawal of consent; and
- site staffing constraints, investigator turnover or limited clinical trial infrastructure.

In addition, because the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our projections of addressable market opportunity for VT-7208 are based on estimates and assumptions that may prove incorrect, and the actual commercial opportunity may be substantially smaller than we expect.

We have made internal estimates of the total addressable market for VT-7208 and other product candidates targeting the BTK pathway, including estimates of patient populations, treatment penetration rates, and potential pricing. These estimates are based on a variety of sources, including published scientific literature, epidemiological data, market research and our own calculations and assumptions about competitive dynamics. However, these estimates are inherently uncertain and may prove to be materially incorrect.

The actual addressable market for VT-7208 may be smaller than we estimate for several reasons, including: the prevalence of food allergy, CSU or MS in the populations we are targeting may be lower than published estimates suggest, or the proportion of patients within those populations for whom BTK inhibition is an appropriate treatment may be more limited than we project, and our efforts to estimate the potential market opportunity for food allergy and CSU is particularly challenging given that treatment options are very early in their approval by the FDA and adoption by patients and providers; physicians may not adopt VT-7208 over established therapies; payors may restrict reimbursement; VT-7208 may initially be approved only for later-line treatment settings with smaller patient populations; competing products may capture significant market share before VT-7208 reaches the market; and advances in autoimmune disease therapies may further segment the patient population. If the actual market opportunity for VT-7208 is materially smaller than our estimates, we may not be able to generate sufficient revenue to justify our development investment, which could have a material adverse effect on our business and financial condition.

Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, cause us to abandon product candidates, could limit the commercial profile of an approved label, or could result in significant negative consequences following any potential marketing approval.

Our clinical trials will include patients suffering from autoimmune diseases, including food allergy, CSU and relapsing MS. It is possible that some of these patients may experience side effects during our clinical trials. Further, BTK inhibitors, including approved and investigational agents such as ibrutinib, acalabrutinib, tolebrutinib, evobrutinib, fenebrutinib, and remibrutinib, have been associated with adverse events including hepatotoxicity (including elevated liver enzymes and drug-induced liver injury), bleeding events (including mucocutaneous bleeding), infections (including opportunistic infections, upper respiratory tract infections, urinary tract infections, and reactivation of latent viral infections), neutropenia, thrombocytopenia, atrial fibrillation, hypertension, diarrhea, nausea, rash, arthralgia, headache, fatigue, and tumor lysis syndrome. Certain BTK inhibitors have also been associated with serious hepatic events, including cases that have led to clinical holds, labeling restrictions, or regulatory delays. For example, evobrutinib and fenebrutinib were each placed on partial clinical hold following cases of liver-enzyme elevation, and the development of tolebrutinib was likewise impacted by hepatic-safety findings. We cannot be certain that hepatic or other toxicity will not occur with the evaluation of VT-7208. While we did not observe any serious adverse events, or any hepatic safety events in our Phase 1 trial, our data are limited by a small sample size, limited drug exposure and treatment of healthy volunteers, and there remains a risk that serious adverse events may be uncovered in clinical trials with greater sample sizes, prolonged exposure to VT-7208 or patient populations with distinct disease characteristics. Further, there can be no assurance that the tolerability profile observed in our preclinical studies will translate to a comparable profile in humans. This risk may be of particular significance given that our Phase 1 trial enrolled only healthy volunteers and our planned Phase 2 trials will be the first evaluation of VT-7208 in patient populations who may respond differently to BTK inhibition. If these or other adverse effects occur with unacceptable frequency or severity in our clinical trials, our ability to develop and commercialize VT-7208 could be materially impaired. In particular, while several BTK inhibitors have been approved for oncology indications, we believe the FDA and comparable foreign regulatory authorities may apply a different risk-benefit threshold for VT-7208 for the treatment of chronic autoimmune diseases such that any harmful side effects that may outweigh the benefits of our product candidate would require us to cease clinical trials or abandon or limit our development of VT-7208 or would cause the FDA or comparable foreign regulatory authorities to deny marketing applications for VT-7208 for chronic autoimmune indications. Accordingly, the risks of negative impact from BTK inhibitors may therefore be higher for our autoimmune programs than for the oncology programs of others. Further, patients may die during our clinical trials for various reasons. The causes of death could include receiving our product candidates because the patient's disease is too advanced or because the patient experiences medical problems that may not be related to our product candidate. Even if the patient deaths are not related to our product candidate, the deaths could affect perceptions regarding the safety of our product candidates. Patient deaths and severe side effects caused by our product candidates, or by products or product candidates of other companies that are thought to have similarities with our product candidates, could result in the delay, suspension, clinical hold or termination of our clinical trials, by the FDA or other regulatory authorities for a number of reasons. If we elect or are required to delay, suspend or terminate any clinical trial of any product candidates that we develop, the commercial prospects of such product candidates will be harmed and our ability to generate product revenues from any of these product candidates would be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of the product candidate at issue. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;

- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;

- we may be required to create a Risk Evaluation and Mitigation Strategy (REMS) plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;

- we may decide to remove such products from the marketplace;

- we could be sued and held liable for harm caused to patients; and

- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

We are targeting chronic autoimmune diseases across multiple distinct indications, which presents additional risks with respect to clinical development, regulatory approvals and commercialization of product candidates.

Our approach of targeting chronic autoimmune diseases, including food allergy, CSU and relapsing MS, presents risks related to the clinical development, regulatory approval and commercialization of our product candidates. We are pursuing three distinct indications simultaneously, each with its own patient population, disease biology, regulatory pathway and competitive landscape, which increases the complexity of our development program and the likelihood that setbacks in one indication could divert resources from or create negative perceptions regarding the others. Additional risks include the following:

- because the autoimmune conditions we are targeting are chronic, non-life-threatening diseases that may require treatment for years or decades, we must demonstrate a safety and tolerability profile suitable for long-term use, which represents a significantly higher bar than is typically required in acute or oncologic settings where greater toxicity may be tolerated in exchange for survival benefit. The prior development of other BTK inhibitors in autoimmune indications has been impeded by tolerability limitations, particularly hepatotoxicity, and regulators, physicians and patients may apply heightened scrutiny to VT-7208 as a result;

- each of our target indications presents distinct clinical heterogeneity that may complicate trial design and interpretation of results. Food allergy involves considerable variability in symptomatic presentation, ranging from mild reactions to life-threatening anaphylaxis. MS encompasses multiple disease subtypes, including relapsing, secondary progressive and primary progressive forms, each with different pathophysiology, natural history and treatment response profiles. This heterogeneity may make it more difficult to design trials that yield statistically significant and clinically meaningful results across our target populations;

- we may face challenges with respect to patient enrollment in our clinical trials, particularly given that we are conducting trials across three distinct indications simultaneously, which may strain our operational resources and limit our ability to recruit sufficient patients at each clinical trial site, as described above;

- our clinical data to date are derived from a Phase 1 trial of 24 healthy volunteers, and our planned Phase 2 trials will involve relatively small sample sizes, which increases the risk of substantial variability in results and reduces the likelihood that outcomes from early-stage trials will be predictive of the success of later-stage, larger clinical trials in patient populations;

- following approval of our product candidates, if any, pricing and level of reimbursement may not be sufficient to offset costs of development, manufacturing, marketing, and commercialization;

- we may have difficulty selecting, validating and achieving clinically meaningful endpoints that are acceptable to regulatory authorities, particularly given that our three target indications use different primary endpoints and outcome measures, and we are relying in part on biomarker and challenge-based endpoints in food allergy and magnetic resonance imaging (MRI)-based endpoints in MS that may not be accepted by regulators as adequate for approval;

- we may have difficulty in accurately diagnosing, stratifying or confirming patients with food allergy, CSU or MS, which could adversely affect enrollment, clinical trial design and interpretation of results. In particular, identifying and confirming immunoglobin E (IgE)-mediated food allergy requires allergen-specific testing and oral food challenges, and stratifying MS patients across relapsing and progressive subtypes requires careful clinical and radiographic assessment;

- regulatory authorities may require larger, longer, additional or different clinical trials than we anticipate, including studies in specific subpopulations or trials designed to address particular safety, efficacy or dosing questions; and

- while the overall patient populations for food allergy, CSU and MS are substantial, the subset of patients within each indication who are appropriate candidates for a BTK inhibitor, and specifically for VT-7208, may be smaller than we estimate, and the competitive landscape in each indication is evolving rapidly as other therapies, including other BTK inhibitors, may reach the market ahead of VT-7208.

Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with product candidates we may develop, are based on estimates. These estimates have been derived from a variety of sources, including published scientific literature, epidemiological data, patient advocacy groups and market research. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. For example, estimates of the prevalence of IgE-mediated food allergy, the number of CSU patients who remain symptomatic despite antihistamine therapy, and the proportion of MS patients with progressive disease may all prove to be different from our assumptions. The number of patients in the United States, Europe and elsewhere may turn out to be lower than expected, and patients may be more difficult to identify and access than our estimates contemplate.

Adverse developments with respect to any of the foregoing could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of any other product candidate we develop.

Any product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations (CROs) or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues may be materially impaired.

Risks Related to Development and our Dependence on Third Parties

We currently rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such clinical trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates.

We currently rely on third-party CROs, academic institutions, study sites, clinical investigators and others to conduct, supervise, and monitor our preclinical studies and clinical trials. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we currently have or plan to enter into agreements governing the activities of these third parties, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to develop VT-7208 and other current and future product candidates, or we may not obtain marketing approval for, or commercialize, VT-7208 or our other current and future product candidates in a timely manner or at all.

Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities could be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical studies are conducted in accordance with the FDA's Good Laboratory Practice (GLP) regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with Good Clinical Practices (GCPs) for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to the development of our product candidates. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by a pandemic limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for current and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize current and future product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for current and future product candidates may be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

We may enter into collaborations for our current or future product candidates or technologies. We cannot control the timing or quantity of resources that our existing or future collaborators will dedicate to research, preclinical and clinical development. Our collaborators may not perform their obligations according to our expectations or standards of quality. Our collaborators could terminate our existing agreements for a number of reasons, many of which may be beyond our control.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we plan to conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of current and future product candidates, which could result in additional losses and deprive us of potential product revenue.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We currently rely on CMOs for the production of VT-7208, and we expect to rely on CMOs for our other product candidates. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We currently have no plans to build our own clinical or commercial-scale manufacturing capabilities for our product candidates. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future preclinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into arrangements with a limited number of third-party contract manufacturing organizations (CMOs) as part of our development of our product candidates. These CMOs will provide drug substance intermediate, device, and drug product that will be subsequently, tested, released, labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of our product candidates or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient (API) necessary to produce product candidates in the quantities needed for our clinical trials or, if any current or future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of any current or future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

The facilities used by third-party manufacturers to manufacture current or future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we do not intend to begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of any of our product candidates. Additionally, any changes implemented by a new CMO would require substantial investment to qualify and validate the vendor as a suitable third party manufacturer of our development or marketed products. Furthermore, we may be required to conduct comparability assessments, which may include additional human clinical studies, in conjunction with validating the new CMO(s).

If any CMO with whom we contract fails to perform its obligations, it could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current and future product candidates and jeopardize our ability to commence product sales and generate revenue.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials or commercial supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidates that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates or products. In addition, in the case of CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

As part of their manufacture of our product candidates, our CMO and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If our CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which could significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of any current or future product candidates for use in clinical trials or for commercial supply;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or second sources of supply with alternative suppliers or CMOs to supplement or supply the raw materials, drug substances, intermediates, and drug product necessary for the manufacture of our product candidates, including VT-7208. If our current third-party CMO cannot perform as agreed, we may be required to replace such manufacturer and we may be unable to replace them on a timely basis or at all.

Because we rely on a single supplier for our drug substance, and a limited number of suppliers for the raw materials used in our drug candidates, any delay, shortage or interruption in the supply of such raw materials or contamination in our manufacturing process could lead to delays in the manufacture and supply of our drug candidates.

We rely on third parties to supply certain raw materials necessary to produce our drug candidates for preclinical studies and clinical trials. For example, BioDuro is currently our single supplier for our drug substance. If BioDuro were unable or unwilling to supply the drug substance to us, we would need to identify an alternative supplier, which would require significant time and expense; however, we believe we could source an alternative supplier if needed. There are a small number of suppliers for certain raw materials that we use to manufacture our drug candidates. Certain of our suppliers or their sub-suppliers are based in China, which exposes us to additional risks including trade restrictions, tariffs, export controls, geopolitical tensions, and potential disruptions to the supply chain that are beyond our control. We work with our CMOs to purchase these materials from our suppliers who may not always have long-term supply agreements in place, which could expose us to a variety of risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to our contract manufacturing caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales with respect to any approved products. Any significant delay in the supply of raw materials for our drug candidates for a preclinical study or a clinical trial due to the need to replace a third-party supplier could considerably delay completion of certain preclinical studies and/or clinical trials. Moreover, if we are unable to purchase sufficient raw materials after regulatory approval for our drug candidates, the commercial launch of our drug candidates could be delayed, or there could be a supply shortage, each of which could impair our ability to generate revenues from their sale.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our drug candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our drug candidates, could adversely impact or disrupt the commercial manufacture or the production of clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Third parties upon which we rely for preclinical and clinical studies may become the subject or target of certain sanctions or restrictions, which may have adverse effects on our operations and business.

Certain foreign contract manufacturing organizations (CMOs) and biotechnology companies may become subject to legislation, trade restrictions, sanctions, tariffs, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities. The BIOSECURE Act, which was signed into law in December 2025 as part of the National Defense Authorization Act for Fiscal Year 2026, prohibits U.S. federal agencies from entering into or renewing any contract, loan, or grant with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract. The Office of Management and Budget (OMB) of the U.S. Government will issue a list of "biotechnology companies of concern," which will include certain companies that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, other entities which the U.S. Government has deemed as such pursuant to a separate designation process, and certain subsidiary, parent, and successor entities of the foregoing. The BIOSECURE Act includes a grandfathering provision providing that the prohibitions shall not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. If any of our third party CMOs or service providers are designated as "biotechnology companies of concern" by OMB, we may be restricted in our ability to work with such companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. As a result, we may need to seek alternative relationships. While we believe we will be able to identify and contract with such alternative vendors, we cannot guarantee that alternative vendors with the necessary capabilities and capacity would be available on a timeline that would not materially delay the development of our therapeutic candidates and cannot predict the terms of any such alternative arrangement nor what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by China or the other countries in retaliation. In addition, any unfavorable government policies on international trade, such as export controls, tariffs, new legislation, renegotiation of existing trade agreements, or any retaliatory trade actions due to recent or future trade tension, may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Regulatory Approval of our Product Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize or will be delayed in commercializing our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, we must obtain marketing approval. Currently, all of our product candidates are in development, and we have not received approval to market any of our product candidates, including VT-7208 for the treatment of food allergy, CSU and relapsing MS, from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. Whether the results from our clinical trials will suffice to obtain approval will be a review issue and the FDA may not grant approval and may require that we conduct one or more additional controlled clinical trials to obtain approval. Additionally, even if the FDA does grant approval for one or more of our product candidates, it may be for a more narrow indication than we seek. Regulatory authorities, including the FDA, also may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contra-indications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of any product candidates we may develop.

We have only limited experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval, if obtained at all, may be delayed. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted NDA, premarket approval application, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our preclinical studies or clinical trials;
- we may not be able to enroll a sufficient number of patients in our clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clinical data are insufficient for approval.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may submit marketing applications in countries other than the United States. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting for our product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which could adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with customers, healthcare professionals, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, administrative civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Our current and future business operations and activities may subject us to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute our product candidates for which we obtain marketing approval. These laws and regulations may restrict or prohibit a wide range of ownership, pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal civil and criminal false claims, including the federal False Claims Act (FCA), which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- Health Insurance Portability and Accountability Act (HIPAA), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act (ACA) require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services (CMS) information related to transfers of value made to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as nurse practitioners and physicians assistants), and teaching hospitals, as well as information regarding ownership and investment interests of such physicians and their immediate family members;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and

- analogous state laws and regulations, such as state anti-kickback and false claims laws may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Some state and local laws require certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales representatives. Further, many state laws governing the privacy and security of health information in certain circumstances, differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, including compensation of physicians with stock or equity awards, could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, integrity oversight and reporting obligations, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our current or future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services (HHS), the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with certain pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;

- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

We are subject to the Bribery Act, the FCPA, and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (the Bribery Act), the Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. Compliance with Trade Control laws may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, Trade Control laws prohibit the provision of certain products and services to countries, governments and persons targeted by sanctions.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally intend to contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Commercialization of our Product Candidates

If we are unable to establish sales, marketing and distribution capabilities for our product candidates, or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if approved.

We have never commercialized a product. To achieve commercial success for any product for which we obtain marketing approval, we will need a sales and marketing organization and establish logistics and distribution processes to commercialize and deliver our product candidates to patients and healthcare providers. We currently plan to work to build our commercialization capabilities internally over time such that we are able to commercialize any product candidate for which we may obtain regulatory approval. However, we currently have no sales, marketing or distribution capabilities and have no experience in marketing or distributing pharmaceutical products. These activities will be expensive and time-consuming and will require significant attention of our executive officers to manage. There are risks involved in establishing our own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Additionally, our beliefs that our products will be commercially viable have not been tested.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we would have to pursue collaborative arrangements regarding the sales and marketing of our products. However, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us, or if we are able to do so, that they would be effective and successful in commercializing our products. Our product revenues and our profitability, if any, would likely to be lower than if we were to sell, market and distribute any product candidates that we develop ourselves. In addition, we would have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates, including VT-7208, effectively.

If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates in the United States or overseas.

We operate in a rapidly changing industry and face significant competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new biopharmaceutical products is highly competitive and subject to rapid and significant technological advancements. We face competition from major multi-national pharmaceutical companies, biotechnology companies and specialty pharmaceutical companies with respect to our current and future product candidates that we may develop and commercialize in the future. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of product candidates for the treatment of autoimmune diseases, including food allergy, CSU and relapsing MS. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Potential competitors also include academic institutions, government agencies and other public and private research organizations.

Remibrutinib, sold by Novartis, is an approved BTK inhibitor for the treatment of CSU, and Xolair (omalizumab), sold by Genentech/Roche, is approved for CSU and food allergy. We are aware of several product candidates in clinical development for the treatment of our target indications, including BTK inhibitors and other approaches. In CSU, we are aware of competitors including Celldex (barzolvolimab), Jasper (briquilimab), Sanofi/Regeneron (dupilumab), Septerna (SEP-631), Sanofi (blu-808), and others. In food allergy, we are aware of competitors including Novartis (remibrutinib), DBV Technologies (Viaskin Peanut), ALK-Abelló (peanut sublingual immunotherapy (SLIT) tablet), RAPT/GSK (ozureprubart), and others. In MS, we are aware of competitors including Sanofi (tolebrutinib), Roche/Genentech (fenebrutinib), Novartis (remibrutinib), Zenas (orelabrutinib), Immunic (vidofludimus calcium), and AB Science (masitinib). Several of these product candidates are in Phase 3 registrational trials with potential approval timelines that are ahead of our development timeline for VT-7208, including Roche's fenebrutinib in Phase 3 for primary progressive MS (PPMS) and Novartis's remibrutinib in Phase 3 for non-relapsing secondary progressive MS (nrSPMS). In addition, we are aware of approved therapies that are used in certain of our target patient populations, including therapies manufactured by Genentech/Roche, Novartis, Sanofi, and others.

Our competitors with development-stage programs may obtain marketing approval from the FDA or other comparable regulatory authorities for their product candidates more rapidly than we do, and they could establish a strong market position before we are able to enter the market. In addition, our competitors may succeed in developing, acquiring or licensing technologies and products that are more effective, more effectively marketed and sold or less costly than any product candidates that we may develop, which could render our product candidates non-competitive and obsolete. Because of our primary focus on autoimmune diseases, if our product candidates achieve marketing approval, we expect to seek premium pricing.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive or better reimbursed than any products that we may commercialize. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position for either their product or a specific indication before we are able to enter the market.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if we obtain approvals from the FDA or other comparable regulatory agencies and are able to initiate commercialization of our product candidates or any other product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, hospitals, including pharmacy directors, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of coverage, adequate reimbursement from, and our ability to negotiate pricing with, third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of comprehensive coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and distribution support.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our product candidates, if approved, may require significant resources and may never be successful. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance could harm our business and could require us to seek additional financing.

Even if our product candidates, if approved, achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates, if approved, that we commercialize will depend in part on the extent to which reimbursement for these products and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may incur significant costs to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, and providers are unlikely to prescribe our products, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products and their administration. Therefore, coverage and adequate reimbursement is critical to new medical product acceptance.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years and biologics that have been on the market for at least eleven (11) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Even if favorable coverage and reimbursement status is attained for one or more product candidates for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Moreover, our positioning of VT-7208 as a treatment option in indications where multiple therapies already exist, including both approved and investigational BTK inhibitors such as remibrutinib, may limit our pricing power and reimbursement potential, as third-party payors may view VT-7208 as an incremental addition to existing treatment options and may impose step therapy, prior authorization or other access restrictions. Physicians may also be reluctant to prescribe a new agent in patient populations where polypharmacy risks are heightened or until the product profile is well established.

Our business, operational and financial goals may not be attainable if the market opportunities for our products are smaller than we expect. Our internal research and third-party estimates may not accurately reflect the market opportunities for VT-7208 or our other product candidates today or in the future.

The total market opportunities that we believe exist are based on a variety of assumptions, calculations and estimates, including the size of the addressable patient population in applicable jurisdictions, the penetration of other drugs in these markets, the number of patients we will test in clinical trials, the price we will be able to charge for our products and the total annual number of patients with food allergy, CSU or MS. In addition, we have relied on third-party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of autoimmune disease patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the number of deaths or severe outcomes caused by food allergy, CSU or MS, and the expected growth in related drug therapy and diagnostic markets. Our internal research and estimates on market opportunities include the use of independent sources, but any or all of our assumptions and/or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our products or such patients becoming difficult to identify and access, limited reimbursement for our products, pricing pressure due to availability of alternative drugs or an inability to obtain the necessary regulatory approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we may not attain our business, operational and financial goals.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for product candidates to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to our Digital Asset Treasury Strategy

Investments in Digital Assets are substantially speculative and have a significant risk of resulting in a loss compared to other forms of investment.

While all investments entail a risk of loss of capital, investments in digital assets such as Chiliz (CHZ) and other cryptocurrencies, tokens, and rights of a similar nature (collectively referred to as, Digital Assets) should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset's status as a "security" in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

The legal test for determining whether any given Digital Asset is a security is a highly complex, fact-driven analysis and the outcome is difficult to predict. The SEC generally does not provide advance guidance or confirmation on the status of any particular asset as a security. The classification of a Digital Asset as a security under applicable law has wide-ranging implications for the regulatory obligations that flow from the offer, sale and trading of such assets. For example, a Digital Asset that is a security in the United States may generally only be offered or sold in the United States pursuant to a registration statement filed with the SEC or in an offering that qualifies for an exemption from registration. Persons that effect transactions in assets that are securities in the United States may be subject to registration with the SEC as a "broker" or "dealer." Platforms that bring together purchasers and sellers to trade Digital Assets that are securities in the United States are generally subject to registration as national securities exchanges, or must qualify for an exemption, such as by being operated by a registered broker-dealer as an alternative trading system (ATS), in compliance with rules for ATSs. Persons facilitating clearing and settlement of securities may be subject to registration with the SEC as a clearing agency. Foreign jurisdictions may have similar licensing, registration, and qualification requirements. As a result, certain Digital Assets may be deemed to be a "security" under the laws of some jurisdictions but not others. Further, various foreign jurisdictions may, in the future, adopt additional laws, regulations, or directives that affect the characterization of Digital Assets as "securities."

We could be subject to legal or regulatory action in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility which may influence our financial results and the market price of our common stock.

Digital Assets have historically experienced, and are expected to continue to experience, high price volatility. Such price fluctuations are likely to influence our financial results and the market price of our common stock. Our financial results and the market price of our common stock would be adversely affected, and our business and financial condition would be negatively impacted, if the price of Digital Assets we hold decrease substantially, including as a result of:

- decreased user and investor confidence in Digital Assets, including due to the various factors described herein;
- investment and trading activities, such as (i) trading activities of highly active retail and institutional users, speculators, miners and investors, (ii) actual or expected significant dispositions of digital assets by large holders, and (iii) actual or perceived manipulation of the spot or derivative markets for digital assets;
- negative publicity, media or social media coverage, or sentiment due to events in or relating to, or perception of, Digital Assets or the broader Digital Assets industry;
- changes in consumer preferences and the perceived value or prospects of Digital Assets;
- competition from other Digital Assets that exhibit better speed, security, scalability, or energy efficiency, that feature other more favored characteristics, that are backed by governments, including the U.S. government, or reserves of fiat currencies, or that represent ownership or security interests in physical assets;
- disruptions, failures, unavailability, or interruptions in service of trading venues for Digital Assets;
- the filing for bankruptcy protection by, liquidation of, or market concerns about the financial viability of digital asset custodians, trading venues, lending platforms, investment funds, or other Digital Asset industry participants;
- regulatory, legislative, enforcement and judicial actions that adversely affect the price, ownership, transferability, trading volumes, legality or public perception of Digital Assets, or that adversely affect the operations of or otherwise prevent digital asset custodians, trading venues, lending platforms or other Digital Assets industry participants from operating in a manner that allows them to continue to deliver services to the Digital Assets industry;
- macroeconomic changes, such as changes in the level of interest rates and inflation, fiscal and monetary policies of governments, trade restrictions, and fiat currency devaluations; and
- developments in mathematics or technology, including in digital computing, algebraic geometry and quantum computing, that could result in the cryptography used by the digital asset blockchain becoming insecure or ineffective.

We may be unable to successfully implement our Digital Asset Strategy.

Our Digital Asset treasury reserve strategy has only been recently approved by our Board. There is no assurance that we will be able to successfully implement this new strategy or operate Digital Asset-related activities at the scale or profitability currently anticipated. Successfully implementing this strategy may present organizational and infrastructure challenges, and we may not be able to fully implement or realize the intended benefits of our strategy. There can be no assurance that we will be successful in implementing our new business strategy. In addition, moving to a new business strategy may result in a loss of established efficiency, which may have a negative impact on our business. We may also face an increased amount of competition as we attempt to expand and grow our business, which may negatively impact our results of operations, cash flows and financial condition.

Our Digital Asset holdings will be less liquid than existing cash and cash equivalents and may not be able to serve as a source of liquidity to the same extent as cash and cash equivalents.

Historically, the Digital Assets markets have been characterized by significant volatility in price, limited liquidity and trading volumes compared to sovereign currencies markets, relative anonymity, a developing regulatory landscape, potential susceptibility to market abuse and manipulation, compliance and internal control failures at exchanges, and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell our Digital Assets at favorable prices or at all. As a result, our Digital Asset holdings may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents. Further, the Digital Assets we intend to hold with our custodians and transact with our trade execution partners does not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. Additionally, we may be unable to enter into term loans or other capital raising transactions collateralized by our unencumbered Digital Assets, or otherwise generate funds using our Digital Asset holdings, including in particular during times of market instability or when the price of a Digital Asset has declined significantly. If we are unable to sell any of our Digital Assets, enter into additional capital raising transactions using any of our Digital Assets as collateral, or otherwise generate funds using our Digital Assets holdings, or if we are forced to sell our Digital Assets at a significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our Digital Assets, we may lose some or all of our Digital Assets and our financial condition and results of operations could be materially adversely affected.

Our Digital Assets are or will be held in custody accounts. We could have a high concentration of Digital Assets in one location or with one custodian, which may be prone to losses arising out of hacking, loss of passwords, comprised access credentials, malware, or cyberattacks. Security breaches and cyberattacks are of particular concern with respect to our Digital Asset holdings. Digital Assets and the entities that provide services to participants in the Digital Asset ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. A successful security breach or cyberattack could result in:

- a partial or total loss of our Digital Assets in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our Digital Assets;
- harm to our reputation and brand;
- improper disclosure of data and violations of applicable data privacy and other laws; or
- significant regulatory scrutiny, investigations, fines, penalties, and other legal, regulatory, contractual and financial exposure.

Further, any actual or perceived data security breach or cybersecurity attack directed at other companies with Digital Assets or companies that operate blockchain networks, regardless of whether we are directly impacted, could lead to a general loss of confidence in the broader blockchain ecosystem or in the use of the digital asset network to conduct financial transactions, which could negatively impact us.

Attacks upon systems across a variety of industries, including industries related to Digital Assets, are increasing in frequency, persistence, and sophistication, and, in many cases, are being conducted by sophisticated, well-funded and organized groups and individuals, including state actors. Any future breach of our operations or those of others in the digital asset industry, including third-party services on which we rely, could materially and adversely affect our financial condition and results of operations.

We face risks relating to the custody of our Digital Assets, including the loss or destruction of private keys required to access our Digital Assets, and cyberattacks or other data loss relating to our Digital Assets.

We hold our Digital Assets with regulated custodians that have duties to safeguard our private keys. Our custodial services contracts do not restrict our ability to reallocate our Digital Assets among our custodians, and our Digital Assets holdings may be concentrated with a single custodian from time to time. In light of the significant amount of Digital Assets we anticipate that we may hold, we continually seek to engage additional custodians to achieve a greater degree of diversification in the custody of our Digital Assets as the extent of potential risk of loss is dependent, in part, on the degree of diversification. If there is a decrease in the availability of Digital Asset custodians that we believe can safely custody our Digital Assets, for example, due to regulatory developments or enforcement actions that cause custodians to discontinue or limit their services in the United States, we may need to enter into agreements that are less favorable than our current agreements or take other measures to custody our Digital Assets, and our ability to seek a greater degree of diversification in the use of custodial services would be materially adversely affected. In addition, holding our Digital Assets with regulated custodians could affect the availability of receiving Digital Assets that may result from "forks" of the blockchain networks if our custodians are unable to support or otherwise provide us with such Digital Assets, thereby reducing the amount of Digital Assets we may hold as a result. While our custodians carry insurance policies to cover losses for commercial crimes, cyber and cold storage, the policy limits vary per provider and would be shared among all of their customers, and subject to various limitations and exclusions (such as if a loss arises due to our failure to protect our login credentials and devices). The insurance that covers losses of our Digital Asset holdings may cover only a small fraction of the value of the entirety of our Digital Asset holdings, and there can be no guarantee that such insurance will be maintained as part of the custodial services we have or that such coverage will cover losses with respect to our Digital Assets. Moreover, our use of custodians exposes us to the risk that the Digital Assets our custodians hold on our behalf could be subject to insolvency proceedings and we could be treated as a general unsecured creditor of the custodian, inhibiting our ability to exercise ownership rights with respect to such Digital Assets. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets.

Digital Assets are controllable only by the possessor of both the unique public key and private key(s) relating to the local or online digital wallet in which the assets are held. While the digital asset blockchain ledger requires a public key relating to a digital wallet to be published when used in a transaction, private keys must be safeguarded and kept private in order to prevent a third party from accessing the digital asset held in such wallet. To the extent the private key(s) for a digital wallet are lost, destroyed, or otherwise compromised and no backup of the private key(s) is accessible, neither we nor our custodians will be able to access the digital asset held in the related digital wallet. Furthermore, we cannot provide assurance that our digital wallets, nor the digital wallets of our custodians held on our behalf, will not be compromised as a result of a cyberattack. The digital asset and blockchain ledger, as well as other Digital Assets and blockchain technologies, have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities.

Our custodially-held Digital Assets may become part of the custodian's insolvency estate if one or more of our custodians enters bankruptcy, receivership or similar insolvency proceedings.

If our Digital Assets held by a custodian are considered to be the property of our custodians' estates in the event that any such custodians were to enter bankruptcy, receivership or similar insolvency proceedings, we could be treated as a general unsecured creditor of such custodians, inhibiting our ability to exercise ownership rights with respect to such Digital Asset and this may ultimately result in the loss of the value related to some or all of such Digital Assets. A series of recent high-profile bankruptcies, closures, liquidations, regulatory enforcement actions and other events relating to companies operating in the Digital Asset industry, including the filings for bankruptcy protection by Three Arrows Capital, Celsius Network, Voyager Digital, FTX Trading and Genesis Global Capital, the closure or liquidation of certain financial institutions that provided lending and other services to the Digital Assets industry, including Signature Bank and Silvergate Bank, SEC enforcement actions against Coinbase, Inc. and Binance Holdings Ltd., the placement of Prime Trust, LLC into receivership following a cease-and-desist order issued by Nevada's Department of Business and Industry, and the filing and subsequent settlement of a civil fraud lawsuit by the New York Attorney General against Genesis Global Capital, its parent company Digital Currency Group, Inc., and former partner Gemini Trust Company, have highlighted the counterparty risks applicable to owning and transacting in Digital Assets. Additional bankruptcies, closures, liquidations, regulatory enforcement actions or other events involving participants in the Digital Asset industry in the future may further negatively impact the adoption rate, price, and use of Digital Assets, limit the availability to us of financing collateralized by Digital Assets that we hold, or create or expose additional counterparty risks. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our Digital Assets. Even if we are able to prevent our Digital Assets from being considered the property of a custodian's bankruptcy estate as part of an insolvency proceeding, it is possible that we would still be delayed or may otherwise experience difficulty in accessing our Digital Assets held by the affected custodian during the pendency of the insolvency proceedings. Any such outcome could have a material adverse effect on our financial condition and the market price of our common stock.

Digital Assets held by us are not subject to FDIC or SIPC protections.

We will not hold our Digital Assets with a banking institution or a member of the Federal Deposit Insurance Corporation (FDIC) or the Securities Investor Protection Corporation (SIPC), and, therefore, our Digital Assets are not subject to the protections enjoyed by depositors with FDIC or SIPC member institutions. As a result, we may suffer a loss with respect to our Digital Assets that is not covered by insurance, and we may not be able to recover any of our carried value in these Digital Assets if they are lost or stolen or suffer significant and sustained reduction in conversion spot price. If we are not otherwise able to recover damages from a malicious actor in connection with these losses, our business and results of operations may suffer, which may have a material negative impact on our stock price.

Digital Assets are novel assets, and are subject to significant legal, commercial, regulatory, and technical uncertainty.

Digital Assets are relatively novel and are subject to rapidly evolving legal, commercial, regulatory, and technical landscapes. Because the application of federal and state securities and other applicable laws, regulations, and rules (Applicable Law) remain unsettled in several material respects, there is substantial risk that a governmental or regulatory authority could adopt or interpret Applicable Law in a manner that adversely affects the price of Digital Assets. Increased regulatory scrutiny may result in additional costs for us and may require our management team to devote increased time and attention to regulatory matters, change aspects of our business, or result in limits on the utility of Digital Assets. Moreover, the regulatory landscape with respect to Digital Assets is rapidly changing and we may be required to comply with any new laws, regulations, or interpretations, which may result in heightened regulatory and compliance related costs, litigation, regulatory investigations, and enforcement or other actions. Adverse changes to, or our failure to comply with Applicable Law may have an adverse effect on our reputation, brand, our business, operating results, and financial condition. Further, if any of our Digital Assets are determined to constitute a security for purposes of U.S. federal securities laws, the additional regulatory restrictions imposed by such a determination could adversely affect the market price of the Digital Assets we hold.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of Digital Assets or the ability of individuals or institutions such as us to own or transfer Digital Assets. Regulatory authorities have been evolving in their approach to Digital Assets. It is not possible to predict whether, or when, any of these developments will lead to U.S. Congress granting additional authorities to the SEC or other regulators, or whether any other federal, state, or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of Digital Asset markets to function or the willingness of financial and other institutions to continue to provide services to the Digital Assets industry, nor how any new regulations or changes to existing regulations might impact the value of Digital Assets generally and any Digital Assets we hold specifically. The consequences of increased regulation of Digital Assets and Digital Asset-related activities could adversely affect the market price of any Digital Assets we hold and in turn adversely affect the market price of our common stock.

Moreover, the risks of engaging in a Digital Asset treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The liquidity of Digital Assets may also be impacted to the extent that changes in Applicable Laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for Digital Assets. The evolving regulatory landscape creates uncertainty for the Company, as new regulations or changes to existing regulations could materially and adversely affect our business operations, financial condition, and results of operations. The effect of any future regulatory change on the Company is impossible to predict, but such change could be substantial and adverse.

We could be subject to legal or regulatory action, including fines, in the event the SEC, a foreign regulatory authority, or a court were to determine that a digital asset held by us is a "security" under applicable laws.

While all investments entail a risk of loss of capital, investments in Digital Assets should be considered substantially more speculative and significantly more likely to result in a loss, including a total loss of capital, than many other forms of investment. The investment characteristics of Digital Assets differ from those of many traditional currencies, commodities, and securities. A particular Digital Asset's status as a "security" in any relevant jurisdiction is subject to a high degree of uncertainty, and if we are unable to properly characterize a Digital Asset, we may be subject to regulatory scrutiny, investigations, fines, and other penalties, which may adversely affect our business, results of operations and/or financial condition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets

We rely upon a combination of patents, trade secret protection, trademarks, and confidentiality agreements to protect the intellectual property related to our product candidates and development programs. Our success depends in large part on our ability to obtain and maintain patents and other intellectual property protection in the United States and in other countries with respect to various proprietary elements of our product candidates, such as, for example, our product formulations and processes for manufacturing our products and our ability to maintain and control the confidentiality of our trade secrets and confidential information critical to our business.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our products that are important to our business. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. There is no guarantee that any patent application we file will result in an issued patent having claims that protect our products; and, as a result, we may not be able to effectively prevent others from commercializing competitive products. Additionally, while the basic requirements for patentability are similar across jurisdictions, each jurisdiction has its own specific requirements for patentability. We cannot guarantee that we will obtain identical or similar patent protection covering our products in all jurisdictions where we file patent applications. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for any product candidate, it could dissuade companies from collaborating with us to develop product candidates and threaten our ability to commercialize any product candidates that are approved. Any such outcome could have a materially adverse effect on our business.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our present and future product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our present or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any present or future product candidates or methods of using such. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent position of biopharmaceutical companies is generally uncertain and involve complex legal and factual questions and has been and will continue to be the subject of litigation and new legislation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, many countries restrict the patentability of methods of treatment of the human body. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain. The pending patent applications that we own or license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries for many reasons. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, considered or cited during patent prosecution, which can be used to invalidate a patent or prevent a patent from issuing from a pending patent application.

Moreover, we may in the future be subject to a third-party pre-issuance submission of prior art to the USPTO. We may also become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competitors from using the technologies claimed in any patents issued to us, which may have an adverse impact on our business. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to prevent third parties from using the same technologies that we use in our product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Generally, issued patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted to recapture a portion of delay by the USPTO in examining the patent application (patent term adjustment) or extended to account for term effectively lost as a result of the FDA regulatory review period (patent term extension), or both. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Method of use patents protect the use of a product for the specified method or indication. In the absence of separate composition of matter protection, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidate(s) for an indication that is outside of the methods of use claimed in our patents. Moreover, even if competitor products are not approved for use in our patented indications, and our competitors do not actively promote their products for indications that are covered by our patents, clinicians may prescribe these competitor products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, such infringement is difficult to prevent or prosecute.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that patent searches, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products or pipeline candidates. We may incorrectly determine that our products are not covered by a third-party patent. Further, we may conclude that a well-informed court or other tribunal would find the claims of a relevant third-party patent to be invalid based on prior art, enablement, written description, or other ground, and that conclusion may be incorrect, which may negatively impact our ability to market our products or pipeline molecules.

Many patents may cover a marketed product, including the composition of the product, methods of use, formulations, cell line constructs, vectors, growth media, production processes and purification processes. The identification of all patents and their expiration dates relevant to the production and sale of a reference product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. We may not identify all relevant patents, or incorrectly determine their expiration dates, which may negatively impact our ability to develop and market our products.

Failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, market and commercialize our products.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. For example, recent decisions raise questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will/will not be viewed in future and whether patent expiration dates may be impacted.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, all European patents, including those issued prior to June 1, 2023, now by default automatically fall under the jurisdiction of a new European Unified Patent Court (the UPC) for litigation involving such patents. As the UPC is a relatively new court system, there is uncertainty regarding litigation at the UPC. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. It is uncertain how the UPC will impact granted European patents in the pharmaceutical industry.

Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications, and the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain key personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for key positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

Third-party claims or litigation alleging infringement of patents or other proprietary rights, or seeking to invalidate our patents or other proprietary rights, may delay or prevent our development and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry, including patent infringement lawsuits, interferences, reexamination, derivation and administrative law proceedings, inter partes review and post-grant review before the USPTO, as well as oppositions and similar processes in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or other business activities may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization.

There may be third-party patents or patent applications with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents covering our product candidates. The existence of any patent with valid and enforceable claims covering one or more of our product candidates could cause substantial delays in our ability to introduce a candidate into the U.S. market if the term of such patent extends beyond our desired product launch date.

There may also be patent applications that have been filed but not published and if such applications issue as patents, they could be asserted against us. For example, in most cases, a patent filed today would not become known to industry participants for at least 18 months given patent rules applicable in most jurisdictions that do not require publication of patent applications until 18 months after filing.

In addition, third parties may obtain patent rights in the future and claim that use of our technologies infringes upon these rights. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms.

Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidate(s), or the use of our product candidate(s). As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use, or sale of our technologies or product candidate(s) or will prevent, limit, or otherwise interfere with our ability to make, use, or sell our technologies and product candidate(s).

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful infringement or other intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our affected products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms.

In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our products. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights.

Third parties may submit applications for patent term extensions in the United States or other jurisdictions where similar extensions are available and/or Supplementary Protection Certificates in the EU states seeking to extend certain patent protection that, if approved, may interfere with or delay the launch of one or more of our product candidates.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Patent litigation and other proceedings may fail, and even if successful, may result in substantial costs and distract our management and other employees. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace.

Furthermore, as the patent landscape is crowded and highly competitive, even in the absence of litigation we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may face commercial competition, which could harm our business. We cannot provide any assurances that third-party patents do not exist which might be enforced against product candidates resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation to third parties.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property rights, including patent rights, that are important or necessary to the development or manufacture of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates. In each of these cases, we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms, or at all, and we could be forced to accept unfavorable contractual terms. If we are unable to obtain such licenses on commercially reasonable terms, our business could be harmed.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. We may not be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may develop or license intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Failure to meet our own obligations to future licensors or upstream licensors, including such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies may provide funding, facilities, personnel, or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may retain rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products. For example, research resulting in future in licensed patent rights and technology that was funded in part by the U.S. government could result in the government having certain rights, or march in rights, to such patent rights and technology which may permit the government to disclose our confidential information to third parties and to exercise march in rights to use or allow third parties to use our licensed technology, potentially on unfavorable terms or without adequate compensation.

We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, written description, or lack of patentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with the prosecution of the patent withheld relevant material information from the USPTO or made a materially misleading statement during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. Because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly and decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention or that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business.

We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the market price of common shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may be subject to claims challenging ownership of intellectual property rights and that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals and retain independent contractors and consultants, or in the future, may employ individuals and retain independent contractors and consultants, who were previously employed at universities or other pharmaceutical companies, including our competitors or potential competitors. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, independent contractors, consultants, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that such persons or other third parties have an ownership interest in our intellectual property.. We may also be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of such persons' former companies or other third parties.. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while we require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us asserting ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights with respect to certain clinical programs.

We are party to certain license agreements with respect to certain of our product candidates outside of our VT-7208 clinical program pursuant to which we were granted rights to intellectual property in connection with the development, manufacture and commercialization of such product candidates. If we fail to comply with our obligations under these agreements or if we are subject to a bankruptcy, we may be required to make certain payments to the licensor of our license or the licensor may have the right to terminate the license, and in the event of termination we may not be able to develop or market products covered by the license. In the event we breach any of our obligations under these agreements, we may incur significant liability to our licensing partners. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patents and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates and that could harm our business.

In addition, our license agreements do, and we expect that future license agreements will, impose various diligence, milestone payment, royalty, insurance and/or other obligations on us. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor(s) may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology, and could compromise our development and commercialization efforts for our product candidates.

We have continuing obligations to make certain operational and financial milestone payments under our license for VT-7208.

We obtained our BTK inhibitor program, including certain compounds and related program assets through an acquisition of a subsidiary of Gossamer Bio, Inc. (Gossamer). There are certain license fees and milestone payments required to be paid by us to Gossamer pursuant to the terms of our agreement with Gossamer (Gossamer Agreement). The Gossamer Agreement requires us to pay one-time development and regulatory milestone payments upon achievement of specified milestone events, up to an aggregate of $165.5 million, tiered net sales-based earn-out payments on sales of products derived from the Gossamer Compounds at rates ranging from low- to mid-single digit percentages depending on certain annual net sales thresholds and up to 5% of the consideration in a qualifying transaction involving a change of control of the Company, sale of the compounds or substantially all of the program assets, subject to certain exceptions. These development and milestone payment obligations could increase our need for additional capital to continue developing VT-7208, the net royalty obligations will reduce any future revenue anticipated from commercialization of VT-7208, if approved, and payments due on any subsequent qualifying transaction may make the Company less attractive to a potential acquiror, all of which could adversely affect our business and financial condition.

We are evaluating strategic opportunities for certain legacy pharmaceutical assets, and any outcome of that evaluation could result in additional costs, delays or dilution.

In addition to VT-7208, we continue to hold certain legacy product candidates outside of our VT-7208 clinical program. We are evaluating a range of strategic opportunities designed to maximize the clinical and long-term value of these legacy assets, which could include continued internal development, out-licensing, partnering, sale, or the contribution of some or all of these assets to a newly formed or spun-out entity. We have not made a final decision as to the path we will pursue for any of these legacy assets, and there is no assurance that we will identify or complete any strategic transaction on favorable terms or at all. Any such transaction, or the failure to complete one, could require us to incur additional costs, including transaction costs, could divert management attention from VT-7208, and, if it involves the issuance of equity or equity-linked securities, could dilute our stockholders. In addition, if we determine to discontinue development of any of these legacy assets, we could incur wind-down costs and remain subject to surviving contractual obligations, such as confidentiality, indemnification or reversion rights in favor of the applicable licensor.

We may be subject to claims challenging the inventorship of our patent filings and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patent applications or patents we may be granted or other intellectual property as an inventor or co-inventor. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any trademarks we may obtain for our product candidates may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

In addition, any proprietary name we propose to use with our product candidates or any other product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

While we have filed patent applications to protect certain aspects of our own proprietary formulation and process developments, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. However, confidential information and trade secrets can be difficult to protect. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors, and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. Moreover, the information embodied in our trade secrets and confidential information may be independently and legitimately developed or discovered by third parties without any improper use of or reference to information or trade secrets. We seek to protect the scientific, technical and business information supporting our operations, as well as the confidential information relating specifically to our product candidates by entering into confidentiality agreements with parties to whom we need to disclose our confidential information, such as, our employees, consultants, board members, contractors, potential collaborators and financial investors. However, we cannot be certain that such agreements have been entered into with all relevant parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. Our confidential information and trade secrets thus may become known by our competitors in ways we cannot prove or remedy.

Although we require all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches.

Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may harm our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the “first-to-file” laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, defending and enforcing patents and trademarks on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may choose not to file patent or trademark applications in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or importing products made using our inventions into the United States or other jurisdictions and we may not be able to use our trademarks in all countries or prevent others from using or registering similar trademarks. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but the ability to enforce our patents is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not being approved, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Governments of some foreign countries may force us to license our patents to third parties on terms that are not commercially reasonable or acceptable to us. In addition, many countries limit the enforceability of patents against government agencies or government contractors. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidate(s). While we will endeavor to try to protect our technologies and product candidate(s) with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive, and unpredictable.

In addition, geopolitical actions in the United States and in other countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement, or defense of our issued patents or those of any future licensors. As a result, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submissions, fee payment and other requirements imposed by governmental patent agencies. Our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. We rely on our outside counsel or third-party vendors to pay these fees. The USPTO, Canadian Intellectual Property Office (CIPO) and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our present and future product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

Risks Related to our Business Operations

We will be required to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need and to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if our product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial and human resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, as the competition for individuals in autoimmune disease product development is high. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and the expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our future success depends on our ability to retain key members of senior management and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biopharmaceutical industry depends upon our ability to attract and retain highly qualified management, research and development, clinical, financial and business development personnel. Our senior management may terminate their employment with us at any time, and we do not maintain "key person" insurance for any of our employees.

As of November 9, 2026, we had 13 full-time employees. Our employees are not represented by labor unions or covered by collective bargaining agreements. We believe that our employee morale is healthy and consider our relationship with our employees to be good.

The Merger resulted in a combined employee and consultant base that is small relative to our development ambitions. We are heavily dependent on a limited number of individuals with specialized expertise in autoimmune diseases and BTK inhibitor development. In addition, many individuals who historically provided services to Vidya Therapeutics, Inc. (Vidya) were, and following the Merger continue to serve the Company as, consultants serving on a part-time basis. The loss of one or more of these individuals, particularly during the critical post-Merger integration period, could significantly delay our clinical development programs. Competition for individuals with this specialized expertise is intense, and we may not be able to recruit suitable replacements on acceptable terms or in a timely manner.

Recruiting and retaining qualified scientific and clinical personnel, in light of the recent merger and, if we progress the development of any of our product candidates, commercialization, manufacturing and sales and marketing personnel, will be critical to our success. The loss of the services of members of our senior management or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing members of our senior management and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize our product candidates. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers, as well as junior, mid-level and senior scientific and medical personnel. Competition to hire from this limited candidate pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Additionally, most of our employees work remotely and because of the challenges of working remotely, their full productivity requires different approaches to onboarding and managing. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited.

We are subject to costs and risks relating to compliance with a variety of federal, state, and local laws pertaining to labor and employment, including employee health and safety, equal employment opportunity, and wage and hour compliance. We may, from time to time, be subject to litigation or administrative actions resulting from claims against us by current or former employees individually or as part of class actions, including claims of wrongful terminations, discrimination, misclassification or other violations of labor law or other alleged conduct. Ensuring the health, safety and well-being of our employees is essential to our operations. We may incur increased costs or disruptions in connection with implementing and maintaining workplace health and safety measures, complying with evolving regulations and guidance, and addressing public health concerns. Any failure to maintain safe and compliant working environments across our facilities and for our distributed workforce could adversely affect our ability to attract and retain personnel and could expose us to liability. We may also, from time to time, be subject to litigation resulting from claims against us by third parties, including claims of breach of non-compete and confidentiality provisions of our employees' former employment agreements with such third parties. Our failure to comply with applicable regulatory requirements could have a material adverse effect on our revenue, business, results of operations and financial condition.

Following the Merger, certain of our consultants who previously worked at a private company are now subject to public company compliance obligations, and any failure to comply with these obligations could expose us to regulatory risk and reputational harm.

As a result of the Merger, a number of individuals who previously operated in a private company environment are now consultants of a publicly traded company and are subject to public company compliance obligations, including compliance with our insider trading policy, Section 16 reporting requirements under the Securities Exchange Act of 1934, Regulation FD restrictions on selective disclosure of material nonpublic information, and quiet period restrictions around SEC filings. These individuals may not have prior experience with public company compliance requirements.

We have implemented onboarding and training programs to educate former Vidya consultants regarding these obligations. However, there can be no assurance that all individuals will fully understand or consistently comply with these requirements, particularly during the initial post-Merger integration period. Any inadvertent violation of insider trading laws, Section 16 reporting obligations, or Regulation FD could result in SEC enforcement action, personal liability for the individuals involved, and reputational harm to the Company. Such violations could also undermine investor confidence in our corporate governance practices and adversely affect the trading price of our common stock.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses, as we may deem appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Additionally, if we undertake future acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expenses. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- reduced resources of our management to pursue our business strategy;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant costs to defend the resulting litigation;
- substantial monetary awards paid to clinical trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently maintain product liability insurance with coverage in the aggregate and a per incident limit at an amount that we believe is adequate to cover estimated liabilities that we may incur. We may need to increase our insurance coverage if we initiate new clinical trials, re-initiate our clinical trials, or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to our Securities and our Status as a Public Company

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the common stock. In addition to the factors discussed elsewhere in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our clinical trials;
- positive or negative results from, or delays in, testing and clinical trials by us, collaborators or competitors;

- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our product candidates and preclinical program;
- changes in the structure and scope of health care payment systems;
- changes to our relationships with collaborators, manufacturers or suppliers;
- concerns regarding the safety of our product candidates;
- announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- the trading volume of our common stock on Nasdaq;
- sales of our common stock by us, members of our senior management and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common stock at or above the price paid for the common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. From time to time, we have been, and may continue to be, subject to legal proceedings and claims in the ordinary course of business. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

Our business and operations could be negatively affected by any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of business and growth strategies and impact our share price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our common stock or other securities or other reasons may in the future cause us to become the target of securities litigation or stockholder activism.

Securities litigation and stockholder activism, including proxy contests, could result in substantial costs and divert management's and the Board's attention and resources from our business. The potential of a proxy contest or other stockholder activism could interfere with our ability to execute on our strategic plan, give rise to perceived uncertainties as to our future direction, result in the loss of potential business opportunities or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. Further, our share price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

Litigation or legal proceedings could expose us to significant liabilities and have a negative impact on our business.

From time to time, we may be party to various claims and litigation proceedings. We evaluate these claims and litigation proceedings to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, we may establish reserves, as appropriate. These assessments and estimates are based on the information available to management at the time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from its assessments and estimates.

On May 10, 2024, we filed a lawsuit against Elion Oncology, Inc. (Elion) disputing the purported termination of our license agreement, dated August 23, 2020 (the Elion License Agreement), with Elion, which lawsuit is subject to counterclaims by Elion. On July 23, 2026, we terminated the Elion License Agreement, by entering into a settlement agreement (the Settlement Agreement) with Elion. Pursuant to the Settlement Agreement, we and Elion agreed to settle all claims in respect of the lawsuit and to terminate the Elion License Agreement without further obligation of either party, with us returning our PCS6422 program to Elion. In connection with the Settlement, we and Elion exchanged mutual releases of all claims relating to the Elion License Agreement, the PCS6422 program and the related litigation. As part of the settlement, we paid Elion the sum of $0.7 million towards Elion's attorneys' fees and/or other out-of-pocket costs. In addition, we agreed to grant to Elion a non-voting equity interest equal to 7.5% of the fully diluted pre-money equity capitalization of any newly formed entity (NewCo) whose assets include one or more of PCS499, PCS11-T and/or PCS12852, if the formation or spin-out of NewCo is completed within one year following the effective date of the Settlement Agreement.

In addition, on December 3, 2024, two of the investors in our February 2021 private offering filed a lawsuit alleging fraud and negligent misrepresentation in connection therewith and seeking monetary damages. The court dismissed two of the three counts of the complaint (for constructive fraud and negligent misrepresentation) and dismissed that part of the remaining cause of action for fraud to the extent that it related to the retention of Plaintiffs' investment (leaving only the portion of the claim in which Plaintiffs allege they were fraudulently induced to invest in the Company in February 2021). In January 2026, Plaintiffs were granted leave to amend their complaint to add a claim for breach of contract against us and David Young. Our and David Young's response to the amended complaint (a motion to dismiss) was submitted on March 2, 2026 and is still pending before the Court. At the Court's request, we also filed a non-substantive submission concerning oral argument. We expect to draft and file a motion for summary judgment in the fourth quarter. We intend to vigorously defend ourselves in this lawsuit and cannot at this time predict the likely outcome of such litigation, reasonably determine either the probability of a material adverse result or any estimated range of potential exposure, or reasonably determine how this matter or any future matters might impact our business, our financial condition, or our results of operations, although such impact, including the costs of defense, as well as any judgments or indemnification obligations, among other things, could be materially adverse to us.

Lawsuits have diverted and may in the future divert our management's attention, and we may incur significant expenses in defending any lawsuits. The results of litigation and other legal proceedings are inherently uncertain, and adverse judgments or settlements in any legal dispute may result in monetary damages, penalties or injunctive relief, or the termination of license agreements, which could have a material adverse effect on our financial position, cash flows or results of operations. While we maintain insurance for certain potential liabilities, such insurance does not cover all types of potential liabilities and is subject to various exclusions, as well as limits on amounts recoverable.

A significant portion of our total outstanding shares may be sold into the market, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our shares of common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements registering the issuance of all shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements will be available for sale in the public market following vesting, exercise and/or settlement (as applicable) of the equity awards and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Furthermore, certain holders of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Finally, in connection with the execution of the Agreement and Plan of Merger (the Merger Agreement), dated as of July 28, 2026, by and among the Company, Vidya, Venus Merger Sub I, Inc., a Delaware corporation and a wholly owned subsidiary of the Company, Venus Merger Sub II, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company, certain of our directors and officers, as well as certain of the directors, officers and stockholders of Vidya, each as of immediately prior to the Merger, entered into lock-up agreements for a period of 180 days following the closing of the Merger, pursuant to which each such stockholder is subject to restrictions on the sale or transfer of shares of our common stock and Series A Preferred Stock held by each such stockholder at the closing, including, in the case of specified officers, directors and stockholders of Vidya, those shares received by them in the Merger, subject to certain limited exceptions as set forth in such lock-up agreements. Upon expiration of this lockup period, these shares will become eligible for sale in the public market. Pursuant to the Merger Agreement and the registration rights agreement that we entered into pursuant to the 2026 Private Placement, we are obligated to prepare and file a resale registration statement with the SEC to register the resale of shares of our common stock underlying the Series A Preferred Stock. We will use reasonable best efforts to cause this registration statement to be declared effective by the SEC. Once the registration statement is declared effective, the shares subject to the registration statement will no longer constitute restricted securities and may be sold freely in the public markets, subject to (i) the approval of the Required Company Stockholder Matters (as defined below), (ii) the approval of the Nasdaq Listing Application (as defined below) and (iii) any beneficial ownership limitations set by the holder of Series A Preferred Stock. Certain additional holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in Securities Act registration statements that we may file for ourselves or other stockholders. If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future.

We do not intend to pay any cash dividends on our common stock in the foreseeable future and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Therefore, you should not rely on an investment in our common stock to provide dividend income. Our board of directors has complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. As a result, capital appreciation, if any, on our common stock will be your sole source of gains for the foreseeable future.

Changes in tax law could adversely affect our business and financial condition.

We are subject to federal, state and local income and other taxes in the United States and in foreign jurisdictions because of the scope of our operations. New tax laws, statutes, rules, regulations or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted differently, changed, repealed or modified at any time. Any such enactment, interpretation, change, repeal or modification could adversely affect us, possibly with retroactive effect. For example, the U.S. government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act that (along with prior U.S. federal tax reform legislation) has resulted in significant changes to the taxation of business entities, including, among other changes, the imposition of minimum taxes and excise taxes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other taxing authorities with respect to this and other legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal law. We continue to evaluate the impact that these and other tax reforms may have on our business. To the extent that any such changes in tax laws and regulations have a negative impact on us, including as a result of related uncertainty, our business, financial condition, results of operations and cash flows may be materially and adversely impacted and we may be required to implement changes to minimize increases in our tax liability.

Our ability to use our NOLs to offset future taxable income may be subject to certain limitations.

Our net operating loss (NOL), carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. U.S. federal NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. Under the Tax Cuts and Jobs Act of 2017 (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), NOLs arising in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of current year taxable income. As of December 31, 2025, we had federal and state net operating loss carryforwards of approximately $54.8 million, of which $54.5 million will not expire and the remainder begin expiring in 2037. Additionally, as of December 31, 2025, we had federal and state research and development tax credits of approximately $1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Code. The federal research and development tax credits have a 20-year carryforward period.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. Following the approval of the Required Company Stockholder Matters, the Merger will result in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after approval of the Required Company Stockholder Matters. Vidya's NOL carryforwards may also be subject to limitations as a result of prior shifts in equity ownership and/or the Merger. We may also have experienced an ownership change in the past, and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. Furthermore, our ability to utilize NOLs of Vidya we have acquired as a result of the Merger may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

We have incurred and expect to continue incurring significantly increased costs as a result of operating as a company whose common stock is publicly traded, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred significant legal, accounting and other expenses that we did not incur previously, as a private company. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we are required to furnish a report by our senior management on our internal control over financial reporting. Depending upon our filer status, we could also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as required by Section 404(b). To prepare for eventual compliance with Section 404, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation, as amended, and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- providing for a classified board of directors with staggered, three-year terms;
- authorizing our board of directors to issue preferred stock with voting or other rights or preferences that could discourage a takeover attempt or delay changes in control;
- prohibiting cumulative voting in the election of directors;
- providing that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- prohibiting the adoption, amendment or repeal of our amended and restated bylaws or the repeal of the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors without the required approval of at least 66.67% of the shares entitled to vote at an election of directors;
- prohibiting stockholder action by written consent;
- limiting the persons who may call special meetings of stockholders; and
- requiring advance notification of stockholder nominations and proposals.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, the provisions of Section 203 of the Delaware General Corporate Law (the DGCL) govern us. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time without the consent of our board of directors.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation, as amended, provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, employees or agents or our stockholders;

- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; and

- any action asserting a claim against us that is governed by the internal-affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. While the Delaware Supreme Court recently determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring such a claim arising under the Securities Act against us, our directors, officers, or other employees in a venue other than in the federal district courts of the United States of America. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation, and this may require significant additional costs associated with resolving such action in other jurisdictions.

Risks Related to the Merger

Pursuant to the terms of the Merger, we are required to recommend that our stockholders approve certain matters, including the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve these matters, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Merger Agreement and the 2026 Private Placement purchase agreement, as promptly as practicable following the date of the Merger Agreement and pursuant to the Nasdaq Stock Market Rules, we are required to call and hold a meeting of our stockholders to obtain the requisite approval from our legacy stockholders for, among other things, (i) the issuance of shares of our common stock upon conversion of Series A Preferred Stock and exercise of certain options held by the former equity holders of Vidya that we assumed in the Merger, which (a) will represent more than 20% of the shares of our common stock outstanding pursuant to Nasdaq Listing Rule 5635(a) and (b) may, together with certain changes to management and our Board of Directors (Board), result in a change of control of the Company pursuant to Nasdaq Listing Rule 5635(b) (the Conversion Proposal), (ii) issuance of shares of our common stock, upon conversion of the shares of Series A Preferred Stock issued in the 2026 Private Placement, pursuant to Nasdaq Listing Rule 5635(d) (the Minimum Price Proposal), (iii) our 2027 Equity Incentive Plan (the EIP Proposal) and (iv) our 2027 Employee Stock Purchase Plan (the ESPP Proposal and, together with the Conversion Proposal, the Minimum Price Proposal and the EIP Proposal, the Required Company Stockholder Matters). If we fail to receive sufficient proxies to constitute a quorum or to obtain the required vote on the Required Company Stockholder Matters or we are otherwise required by Nasdaq Listing Rules, we would be required to adjourn or postpone the meeting one or more times for up to 30 days per adjournment or postponement. If stockholder approval of the Required Company Stockholder Matters is still not obtained following such adjournment(s) or postponement(s), we will be obligated to continue soliciting stockholder approval at subsequent annual or special meetings of our stockholders, held at intervals of at least every six months, until such approvals are obtained, which would be time consuming and costly.

There can be no assurance that our legacy stockholders will approve the Required Company Stockholder Matters. If our legacy stockholders do not approve the Conversion Proposal, we would be unable to issue the additional shares of our common stock necessary to complete the conversion of Series A Preferred Stock into our common stock, and may be unable to satisfy our other capital needs, which could have a material adverse effect on our business, financial condition, and prospects.

There can be no assurance that our legacy stockholders will approve the Required Company Stockholder Matters. Additionally, if the Conversion Proposal is not approved by the date that is nine months following the initial issuance date of the Series A Preferred Stock, the holders of the Series A Preferred Stock would be entitled to require us to settle their shares of our common stock underlying the Series A Preferred Stock for cash at a price per share equal to the fair value of our common stock at such time as described in the Certificate of Designation, provided that the Company has funds legally available for such payment. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series A Preferred Stock, it could materially affect our results of operations, business and financial condition.

Failure to obtain approval of the Nasdaq Listing Application, if required, could materially affect our results of operations, business and financial condition.

Pursuant to the Merger Agreement, we are required to use our reasonable best efforts to file the Nasdaq Listing Application to the extent required by the Nasdaq Listing Rules and to cause such Nasdaq Listing Application to be conditionally approved prior to the date of our stockholder meeting to approve the Required Company Stockholder Matters. Approval of a Nasdaq Listing Application may be required if Nasdaq determines there is a "change of control" under Nasdaq Listing Rule 5110(a). If we fail to meet the Nasdaq initial listing requirements and Nasdaq does not approve the Nasdaq Listing Application if and when required, we may be required to adjourn or postpone our stockholder meeting to approve the Required Company Stockholder Matters one or more times for up to 30 days per adjournment, continue to use our reasonable best efforts to obtain approval of the Nasdaq Listing Application and to continue soliciting stockholder approval of the Required Company Stockholder Matters at subsequent annual or special meetings of our stockholders, held at intervals of at least every six months, until such approval and the approval of the Required Company Stockholder Matters are obtained, which would be time consuming and costly. Additionally, if the Conversion Proposal is not approved by the date that is nine months following the initial issuance date of the Series A Preferred Stock, the holders of the Series A Preferred Stock would be entitled to require us to settle their shares of Series A Preferred Stock for cash at a price per share equal to the fair value of the Series A Preferred Stock at such time as described in the Certificate of Designation, provided that the Company has funds legally available for such payment. If we are forced to cash settle a significant amount of the shares of our common stock underlying the Series A Preferred Stock, it could materially affect our results of operations, business and financial condition. We cannot assure you that we will be able to meet Nasdaq's initial listing standards if required. Furthermore, if we fail to obtain approval of the Nasdaq Listing Application to the extent required, we may be unable to execute on our plans for the Company following the Merger, which could materially affect our results of operations, business and financial condition.

There is no guarantee that the Merger will increase stockholder value.

In July 2026, we consummated the Merger, pursuant to which we acquired Vidya, and we closed the 2026 Private Placement. We cannot guarantee that implementing the Merger and related transactions will not impair stockholder value or otherwise adversely affect our business. The Merger poses significant integration challenges between our businesses and employees which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Merger to our stockholders.

The failure to successfully integrate the businesses of the Company and Vidya in the expected timeframe could adversely affect our results of operations, financial condition, and future results.

Our ability to successfully integrate the operations of the Company and Vidya will depend, in part, on our ability to realize the anticipated benefits from the Merger. If we are not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits of the Merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the integration of the Company's and Vidya's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. There can be no assurance that we will effectively manage the increased complexity of our business without experiencing operating inefficiencies or control deficiencies. Delays encountered in the integration process could have a material adverse effect on our expenses, operating results and financial condition, including the value of shares of our common stock.

We expect to incur substantial expenses related to the integration of Vidya.

We have incurred, and expect to continue to incur, substantial expenses in connection with the Merger and the integration of Vidya. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including accounting and finance, billing, payroll, and benefits. Both the Company and Vidya have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement, and the related ancillary agreements. While we have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present.

General Risk Factors

Our business, operations and clinical development plans and timelines, as well as the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, CROs, shippers, equipment suppliers and others, could be adversely affected by the effects of health epidemics.

Our business could be adversely affected by health epidemics wherever we have clinical trial sites or other business operations. In addition, health epidemics could cause significant disruption in the operations of third-party manufacturers, CROs and other third parties upon whom we rely. The effects of government orders may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

If our relationships with our suppliers or other vendors are terminated or scaled back as a result of health epidemics, we may not be able to enter into arrangements with alternative suppliers or vendors or do so on commercially reasonable terms or in a timely manner. Switching or adding additional suppliers or vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new supplier or vendor commences work. As a result, delays may occur, which could adversely impact our ability to meet our desired clinical development and any future commercialization timelines. Although we carefully manage our relationships with our suppliers and vendors, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not harm our business.

In addition, our preclinical studies and clinical trials may be affected by health epidemics. Clinical site initiation, patient enrollment and activities that require visits to clinical sites, including data monitoring, may be delayed due to prioritization of hospital resources toward the pandemic or concerns among patients about participating in clinical trials during a pandemic. Some patients may have difficulty following certain aspects of clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. These challenges may also increase the costs of completing our clinical trials. Similarly, if we are unable to successfully recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure or experience additional restrictions by their institutions, city or state, our clinical trial operations could be adversely impacted.

If our information systems or data, or those of our collaborators, contractors, consultants or other third parties with whom we work, are or were compromised, we could experience adverse consequences, including but not limited to regulatory investigations or actions; litigation; fines and penalties; significant disruption of our product development programs and our ability to operate our business effectively; reputational harm; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work, process, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share,, (collectively, process), proprietary, confidential, and sensitive data, including personal data, intellectual property, trade secrets and clinical trial data, (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, security, integrity, and availability of our sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some threat actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to conduct our clinical trials and other business.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to computer viruses, malicious or unintentional actions or inactions that cause vulnerabilities, malware, software or hardware failure, supply chain attacks, social engineering (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential stuffing, ransomware, unauthorized access, attacks enhanced or facilitated by artificial intelligence, ("AI"), natural disasters, terrorism, war and telecommunication and electrical failures. In particular, ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe, and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Future and past business transactions (such as acquisitions or mergers) expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers introduce cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover damages, or we may be unable to recover such awards. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Remote work has also increased risks to our information systems and data, as personnel utilize network connections, computers and devices outside of our premises or network.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities, including on a timely basis. Further, we have and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident or other interruption that have in the past and may in the future result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, including where required by applicable data privacy and security laws or regulations or industry standards. Certain data privacy and security obligations require us to implement and maintain certain security measures.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, this could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information, significant delays or setbacks in our research, or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Such an actual or perceived security incident could also cause us to experience other adverse consequences, such as: loss of, or damage to, our data or applications, inappropriate disclosure of confidential or proprietary information, legal liability, exposure to litigation (including class claims) and regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, harm to our competitive position, reputational damage, and delay in the further development and commercialization of our product candidates.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveal competitively sensitive details about the company and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of ours could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative, agentic and other artificial intelligence (AI) technologies.

We and the third parties with whom we work are subject to rapidly changing and increasingly stringent U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies and other obligations relating to privacy, data protection and information security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with these obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of business operations (including clinical trials); reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process personal data and other sensitive information. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous privacy and data security laws, including federal and state health information privacy laws, federal and state security breach notification laws, federal and state consumer protection laws, and other similar laws (e.g., wiretapping laws). For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, many states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act (CCPA) applies to personal data of consumers, business representatives, and employees who are California residents and requires businesses subject to the CCPA to provide specific disclosures in privacy notices and respond to requests of such individuals to exercise certain rights concerning their personal data. The CCPA provides fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other U.S. state comprehensive consumer privacy laws exempt certain personal data processed in connection with clinical trials, these developments could further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels, and we expect more governments to pass similar laws in the future. The evolving patchwork of local, state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third party litigation and regulatory investigations, enforcement, fines, and penalties.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR) the United Kingdom's General Data Protection Regulation (UK GDPR) (collectively, GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), Australia's Privacy Act, and India's Information Technology Act and supplementary rules, impose strict requirements for processing personal data. The EU GDPR and UK GDPR govern the collection, use, disclosure, transfer or other processing of personal data of European Economic Area (EEA) and UK residents, respectively. Among other things, the EU GDPR and UK GDPR impose requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, stipulate the lawful bases on which personal data can be processed, establish broad definitions of personal data and require changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The EU GDPR and UK GDPR also provide for substantial fines for breaches and violations (up to the greater of €20 million under the EU GDPR or £17.5 million under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater). The EU GDPR and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the EU GDPR and UK GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries including in connection with our clinical trials. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally, the U.S. Department of Justice issued a rule entitled Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restrictions on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are considered "foreign persons" and majority owned by, organized under the laws of, primarily resident in, or a contractor of a covered person or country of concern, as applicable) that impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In addition to data privacy and security laws, we are and may in the future become bound by contractual obligations and industry standards related to data privacy and security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

We increasingly use AI and machine learning tools across our operations and business functions, and we expect our use of such tools to expand over time. While we believe that the responsible use of AI tools can enhance our operational efficiency, these tools present risks that could adversely affect our business. AI-generated outputs may be inaccurate, incomplete, or misleading, and reliance on such outputs could result in errors in regulatory submissions as well as clinical or scientific analyses, non-compliance with relevant obligations (such as laws and contracts), and/or necessitate public disclosures. In addition, the input of proprietary, confidential, or sensitive information into third-party AI platforms could result in the inadvertent disclosure of trade secrets, attorney-client privileged materials, or material nonpublic information. The regulatory landscape governing the use of AI, including in the life sciences and pharmaceutical industries, is rapidly evolving, and such developments could impose additional compliance obligations and costs, restrict certain uses of AI tools, and/or increase our exposure to regulatory enforcement actions or litigation. Any failure to adequately govern our use of AI tools could result in reputational harm, regulatory scrutiny, legal liability and other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy obligations) are quickly changing, becoming increasingly stringent, and creating uncertainty. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations have in the past and may in the future necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change aspects of our business model or our clinical trials.

Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we (or third parties with whom we work) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; orders to destroy or not use personal data; and/or imprisonment of company officials. In particular, plaintiffs have become increasingly active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including our clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our vendors and suppliers, could be subject to power shortages, telecommunications failures, water shortages, civil unrest, labor disputes, violence, earthquakes, floods, hurricanes, typhoons, fires, extreme weather conditions, infectious disease, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We currently rely on third-party suppliers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our common stock could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. As a public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we continue to have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended September 30, 2026, none of our directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

SEC Ref. No.	Title of Document
2.1	Agreement and Plan of Merger, dated July 28, 2026, by and among Processa Pharmaceuticals, Inc., Venus Merger Sub I, Inc., Venus Merger Sub II, LLC and Vidya Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)
3.1	Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1 to Form S-1 (File No. 333-235511), filed on September 17, 2020)
3.1.1	Amendment to Fourth Amended and Restated Certificate of Incorporation of Heatwurx, Inc. (incorporated by reference to Exhibit 3.1.1 to Form S-1 (File No. 333-235511), filed on September 17, 2020)
3.1.2	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated August 8, 2019 (incorporated by reference to Exhibit 3 to Form 10-Q (File No. 001-39531), filed on August 14, 2019)
3.1.3	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. dated June 25, 2020 (incorporated by reference to Exhibit 3.1.4 to Form S-1 (File No. 333-235511), filed on September 17, 2020)
3.1.4	Certificate of Amendment to Fourth Amended and Restated Certificate of Incorporation dated January 1, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K (File No. 001-39531), filed on January 6, 2022)
3.1.5	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K (File No. 001-39531), filed on June 29, 2023)
3.1.6	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K (File No. 001-39531), filed on January 18, 2024)
3.1.7	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K/A (File No. 001-39531), filed September 16, 2025)
3.1.8	Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of Processa Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Form 8-K (File No. 001-39531), filed December 15, 2025)
3.2	Certificate of Designation of Series A Non-Voting Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)
3.3	Amended and Restated Bylaws of Processa Pharmaceuticals, Inc., dated March 18, 2025 (incorporated by reference to Exhibit 3.2 to Form 10-K (File No. 001-39531), filed on March 20, 2025)
10.1	Form of Securities Purchase Agreement, dated as of July 28, 2026, by and among Processa Pharmaceuticals, Inc. and each investor listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)
10.2	Form of Registration Rights Agreement, by and among Processa Pharmaceuticals, Inc. and the investors signatory thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on July 29, 2026)
10.3+	Amended and Restated Processa Pharmaceuticals, Inc. 2019 Omnibus Incentive Plan (incorporated by reference to Appendix A of Schedule DEF 14A filed on June 18, 2026)
10.4+	Employment Agreement by and between Gregory J. Flesher and Processa Pharmaceuticals, Inc., dated November 3, 2026 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-39531), filed with the SEC on November 4, 2026)
31.1*	Rule 13a-14(a) Certification of Principal Executive Officer
31.2*	Rule 13a-14(a) Certification of Principal Financial Officer
32.1*++	Section 1350 Certification of Principal Executive Officer and Principal Financial Officer
99.1	XBRL Files
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Management contract or compensatory plan or arrangement.

++ This certification is being furnished solely to accompany this Quarterly Report pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROCESSA PHARMACEUTICALS, INC.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Dated: November 13, 2026

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Dated: November 13, 2026

Exhibit 31.1

CERTIFICATION

I, George Ng, Chief Executive Officer of PROCESSA PHARMACEUTICALS, INC. certify that:

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the quarter ended September 30, 2026;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: November 13, 2026

Exhibit 31.2

CERTIFICATION

I, Russell Skibsted, Chief Financial Officer of PROCESSA PHARMACEUTICALS, INC. certify that:

1. I have reviewed this quarterly report on Form 10-Q of PROCESSA PHARMACEUTICALS, INC. for the quarter ended September 30, 2026;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: November 13, 2026

Exhibit 32.1

Certification of the Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. §1350

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of Processa Pharmaceuticals, Inc. (the "Company"), hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2026 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

By: */s/ George Ng*
George Ng
Chief Executive Officer
(Principal Executive Officer)
Date: November 13, 2026

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and 18 U.S.C. §1350, I, the undersigned Chief Financial Officer of the Company, hereby certify, to the best of my knowledge, that the Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350 and is not being filed for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

By: */s/ Russell Skibsted*
Russell Skibsted
Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: November 13, 2026